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**Fennell et al.**

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(54) **METHOD AND DEVICE FOR DETERMINING ELAPSED SENSOR LIFE**

(71) Applicant: **Abbott Diabetes Care Inc.**, Alameda, CA (US)

(72) Inventors: **Martin J. Fennell**, Concord, CA (US); **Saeed Nekoomaram**, San mateo, CA (US)

(73) Assignee: **Abbott Diabetes Care Inc.**, Alameda, CA (US)

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(58) **Field of Classification Search**

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See application file for complete search history.

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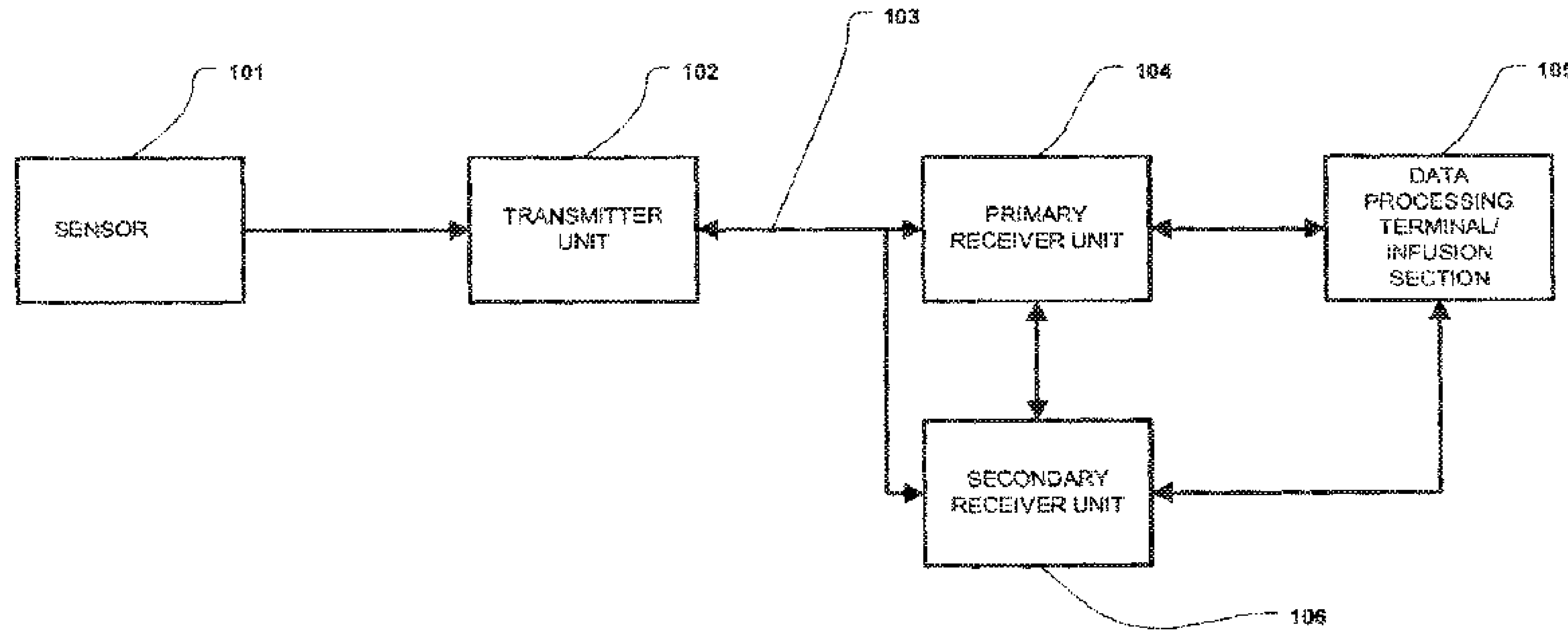
*Primary Examiner* — Sisay Yacob

(74) *Attorney, Agent, or Firm* — Jackson & Co., LLP

(57) **ABSTRACT**

Methods and systems for determining elapsed sensor life in medical systems, and more specifically continuous analyte monitoring systems.

**18 Claims, 16 Drawing Sheets**

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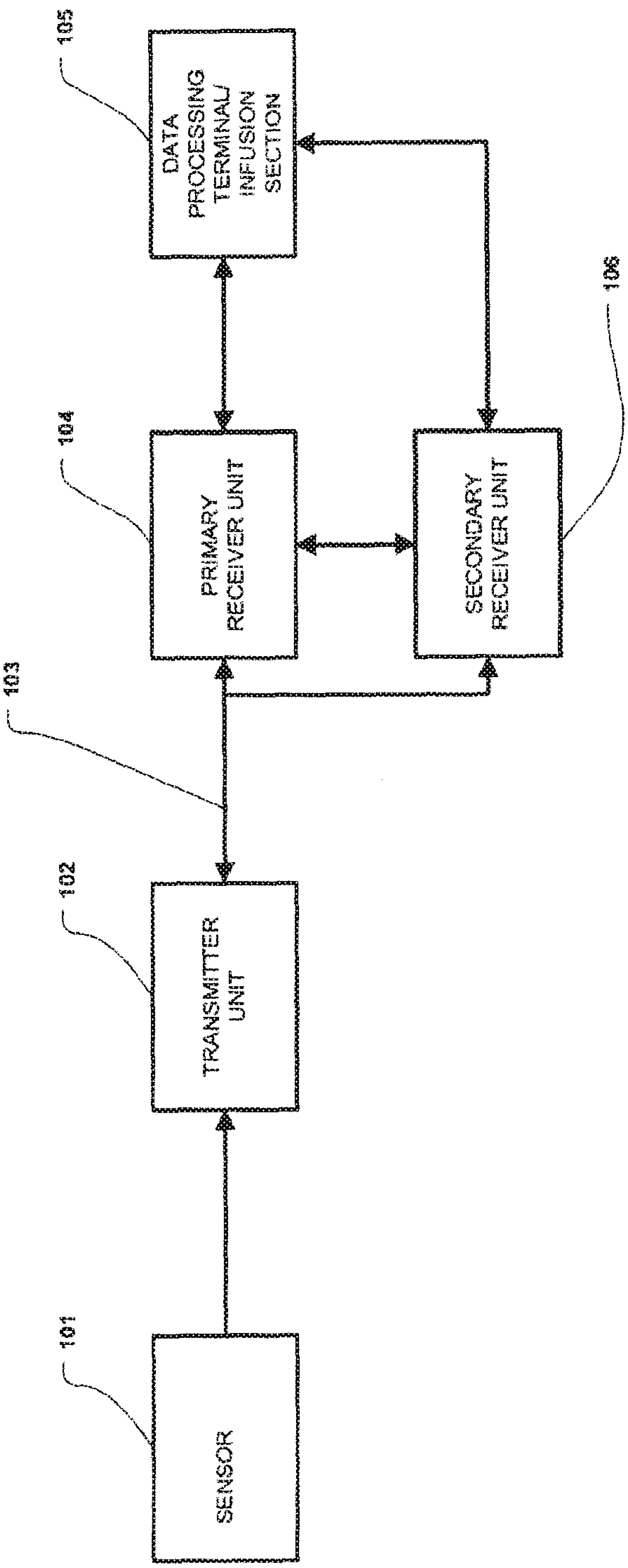
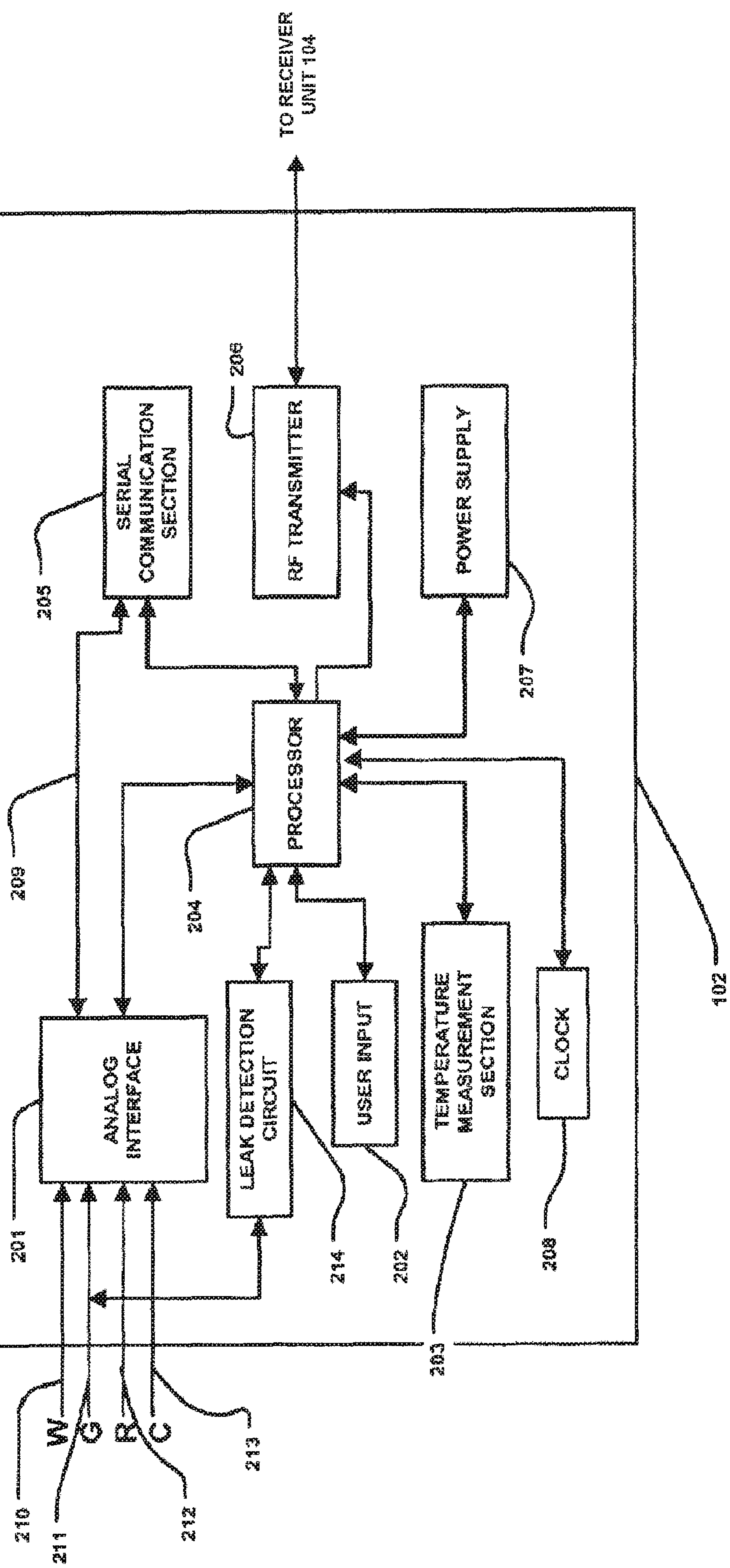

SENSOR
101
TRANSMITTER UNIT
102
103
PRIMARY RECEIVER UNIT
104
DATA PROCESSING TERMINAL/ INFUSION SECTION
105
SECONDARY RECEIVER UNIT
106

100

FIGURE 1



TO RECEIVER UNIT 104
SERIAL COMMUNICATION SECTION
RF TRANSMITTER
POWER SUPPLY
PROCESSOR
ANALOG INTERFACE
LEAK DETECTION CIRCUIT
USER INPUT
TEMPERATURE MEASUREMENT SECTION
CLOCK
W
G
R
C
102
201
202
203
204
205
206
207
208
209
210
211
212
213
214


FIGURE 2

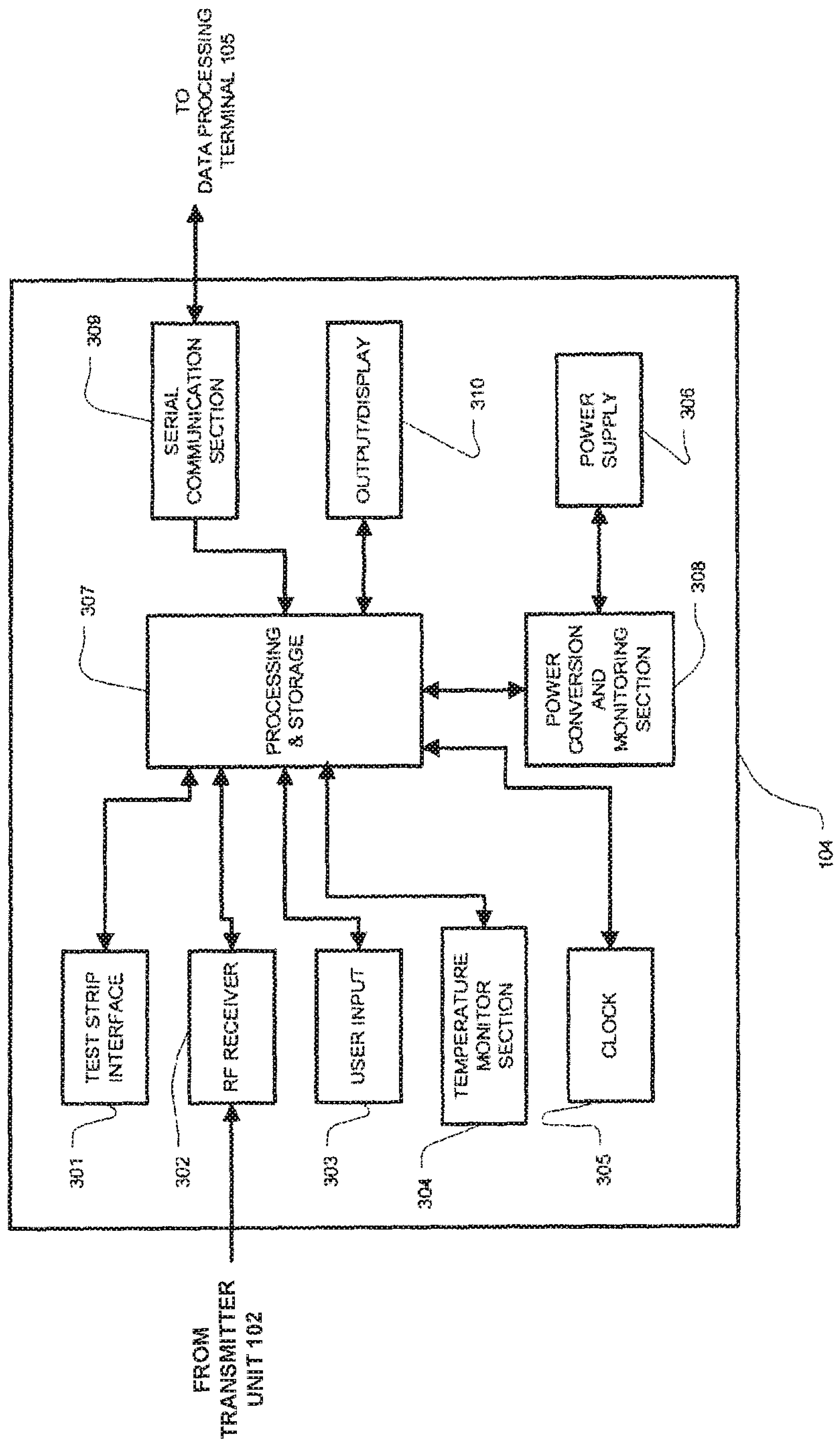

TO
DATA PROCESSING
TERMINAL 105
309
SERIAL
COMMUNICATION
SECTION
OUTPUT/DISPLAY
310
POWER
SUPPLY
306
307
PROCESSING
& STORAGE
POWER
CONVERSION
AND
MONITORING
SECTION
308
TEST STRIP
INTERFACE
RF RECEIVER
USER INPUT
TEMPERATURE
MONITOR
SECTION
CLOCK
301
302
303
304
305
104
FROM
TRANSMITTER
UNIT 102

FIGURE 3

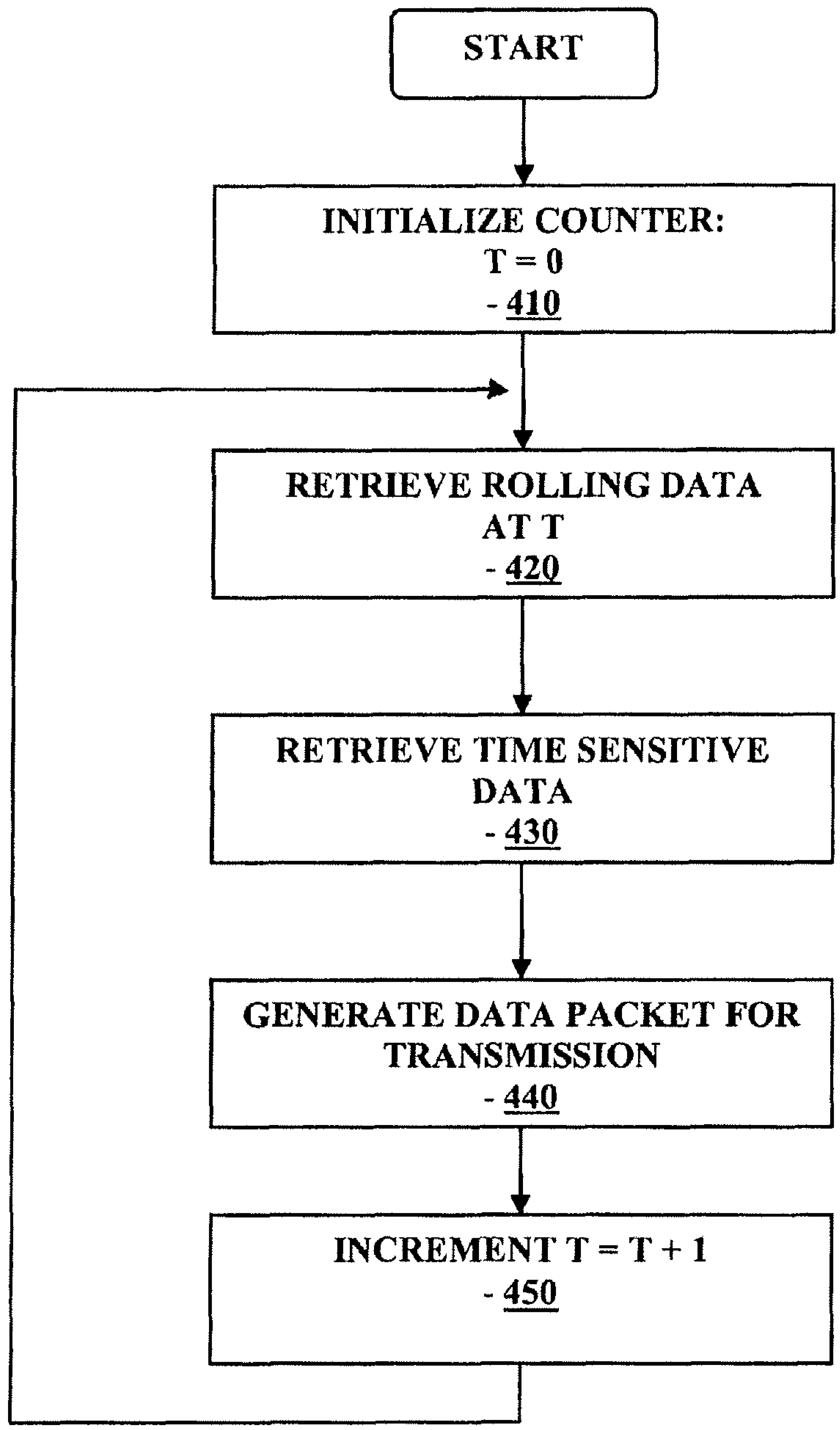

START
INITIALIZE COUNTER:
T = 0
- 410
RETRIEVE ROLLING DATA
AT T
- 420
RETRIEVE TIME SENSITIVE
DATA
- 430
GENERATE DATA PACKET FOR
TRANSMISSION
- 440
INCREMENT T = T + 1
- 450

FIGURE 4

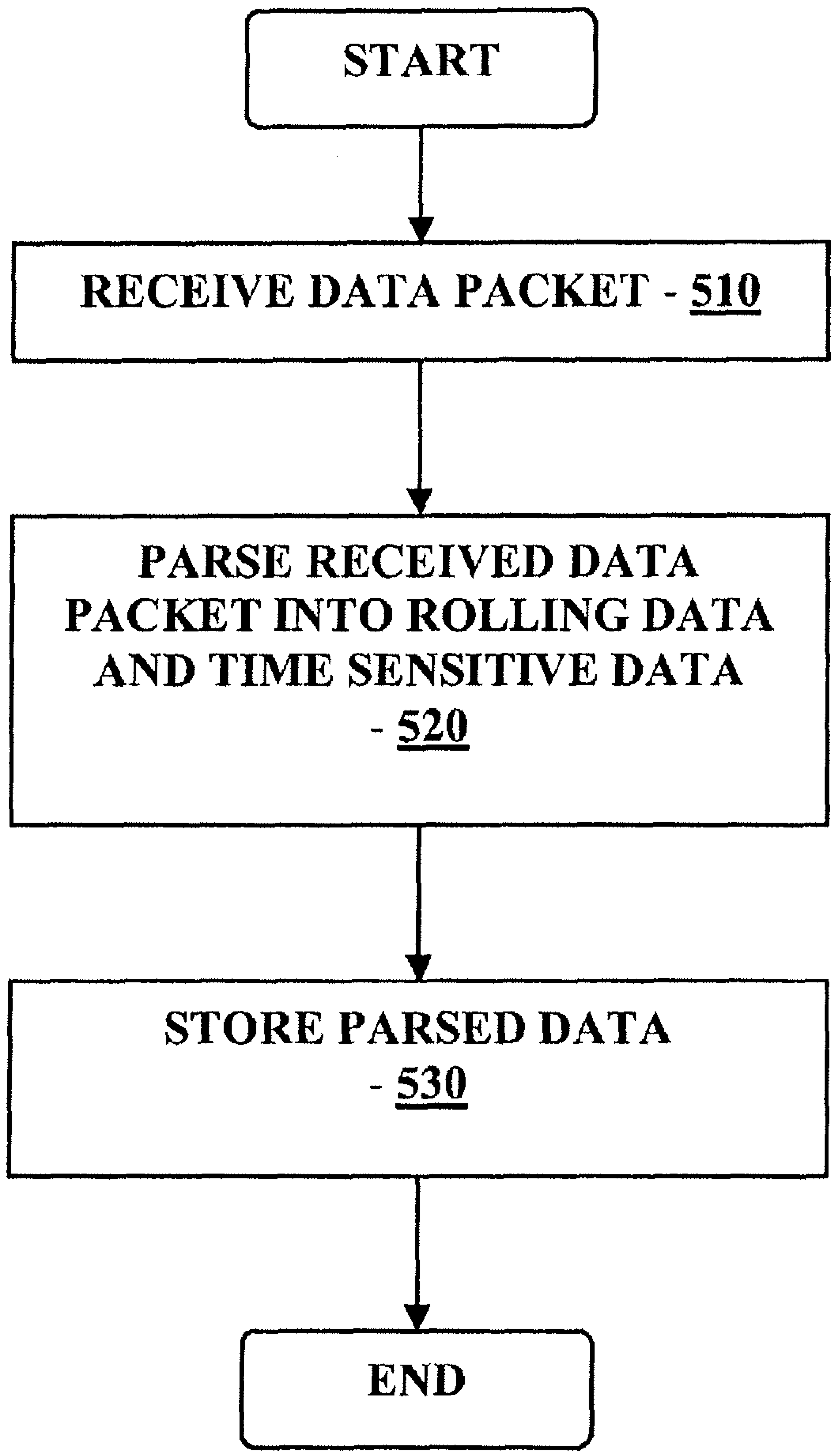
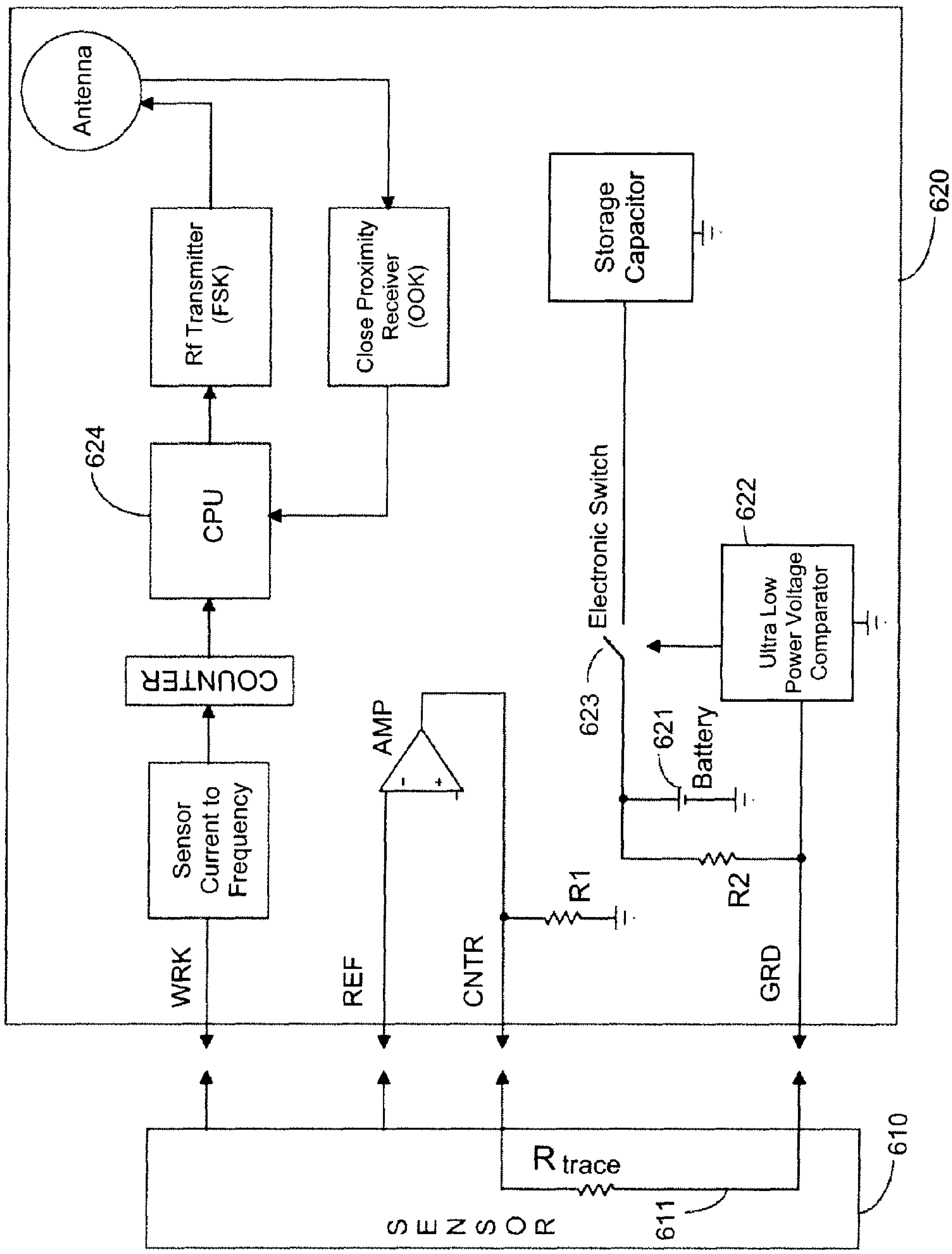

START
RECEIVE DATA PACKET - 510
PARSE RECEIVED DATA PACKET INTO ROLLING DATA AND TIME SENSITIVE DATA - 520
STORE PARSED DATA - 530
END

FIGURE 5



Antenna
Rf Transmitter (FSK)
Close Proximity Receiver (OOK)
Storage Capacitor
620
624
CPU
Electronic Switch
622
Ultra Low Power Voltage Comparator
COUNTER
AMP
623
621
Battery
Sensor Current to Frequency
R1
R2
WRK
REF
CNTR
GRD
R trace
610
611
SENSOR


FIGURE 6

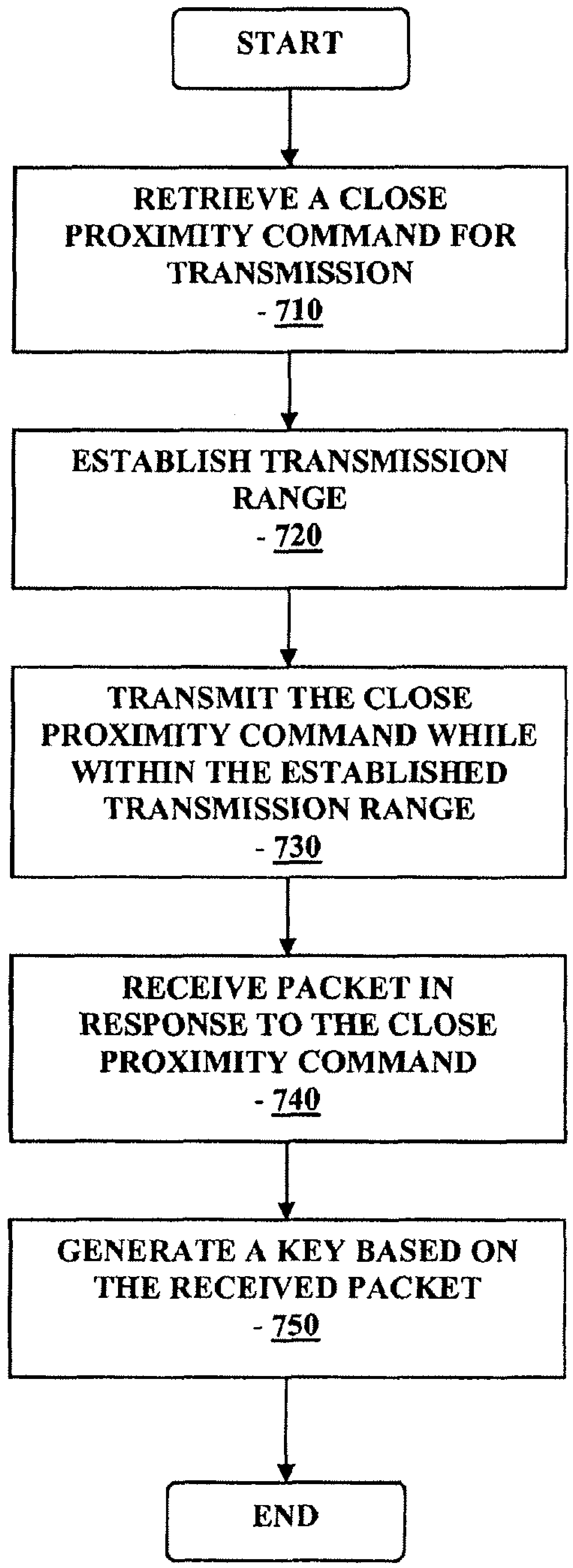

START
RETRIEVE A CLOSE PROXIMITY COMMAND FOR TRANSMISSION
- 710
ESTABLISH TRANSMISSION RANGE
- 720
TRANSMIT THE CLOSE PROXIMITY COMMAND WHILE WITHIN THE ESTABLISHED TRANSMISSION RANGE
- 730
RECEIVE PACKET IN RESPONSE TO THE CLOSE PROXIMITY COMMAND
- 740
GENERATE A KEY BASED ON THE RECEIVED PACKET
- 750
END

FIGURE 7

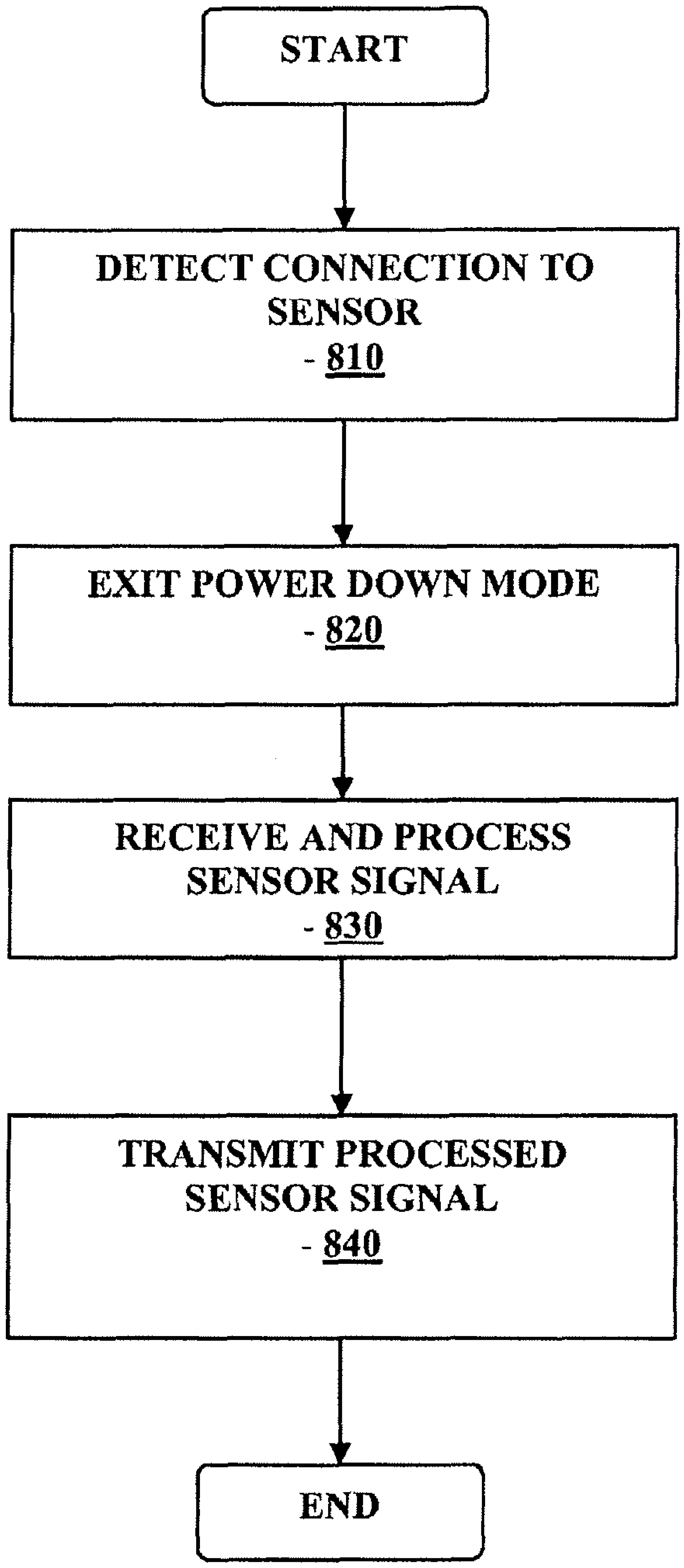

START
DETECT CONNECTION TO SENSOR
- 810
EXIT POWER DOWN MODE
- 820
RECEIVE AND PROCESS SENSOR SIGNAL
- 830
TRANSMIT PROCESSED SENSOR SIGNAL
- 840
END

FIGURE 8

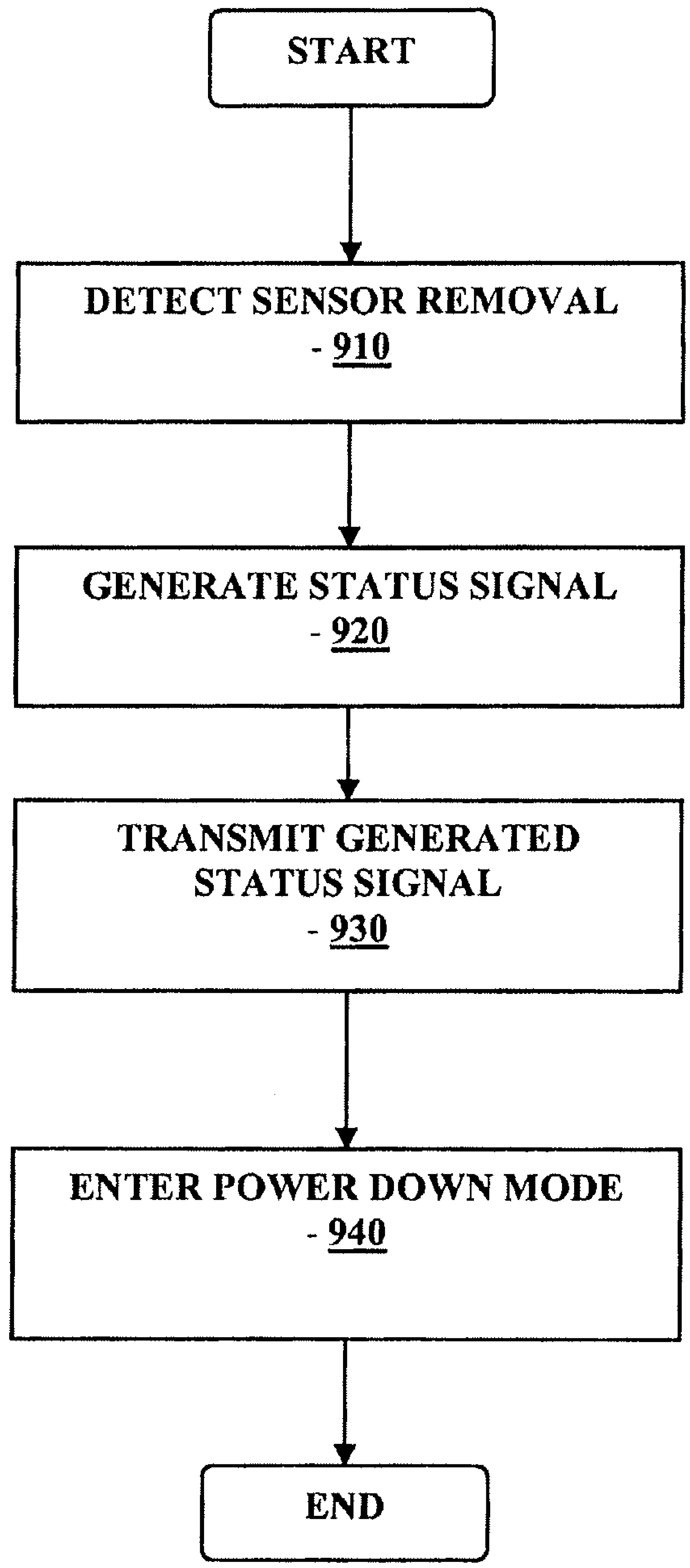

START
DETECT SENSOR REMOVAL - 910
GENERATE STATUS SIGNAL - 920
TRANSMIT GENERATED STATUS SIGNAL - 930
ENTER POWER DOWN MODE - 940
END

FIGURE 9

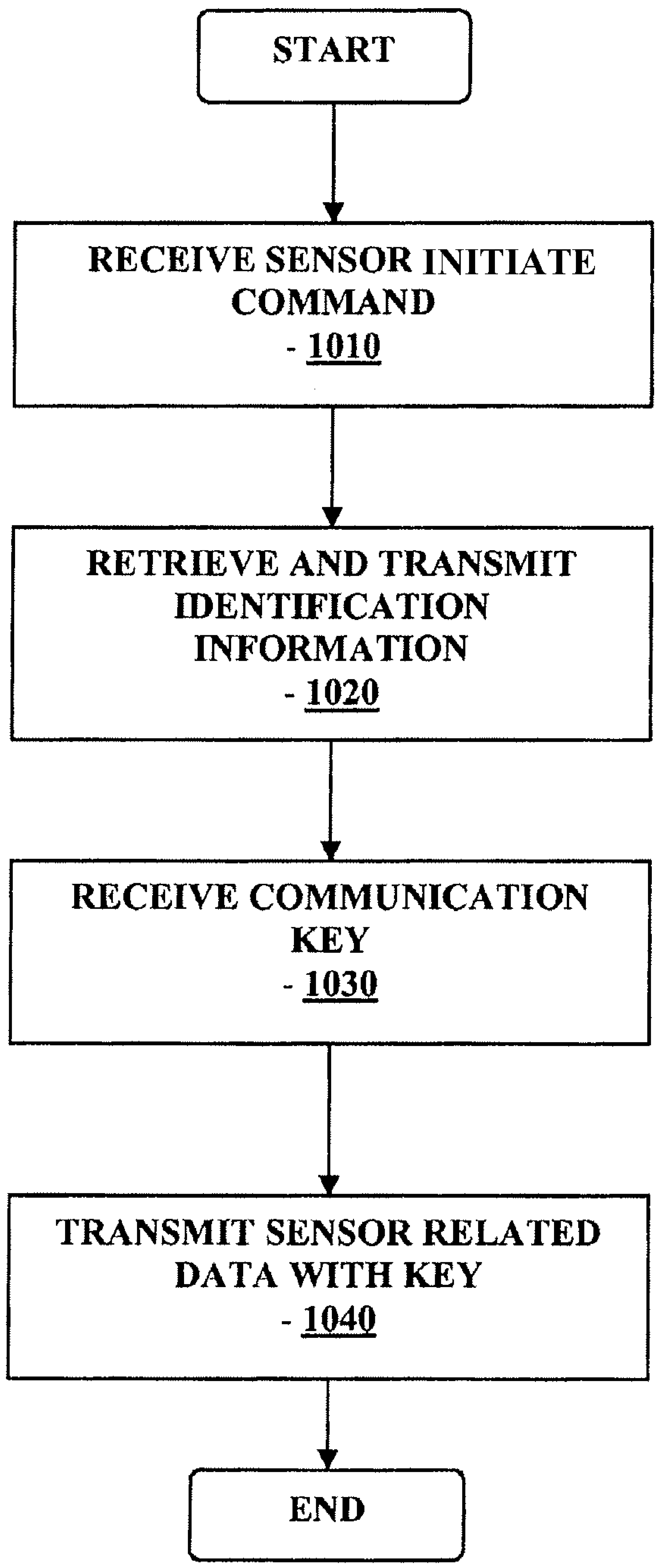

START
RECEIVE SENSOR INITIATE COMMAND
- 1010
RETRIEVE AND TRANSMIT IDENTIFICATION INFORMATION
- 1020
RECEIVE COMMUNICATION KEY
- 1030
TRANSMIT SENSOR RELATED DATA WITH KEY
- 1040
END

FIGURE 10

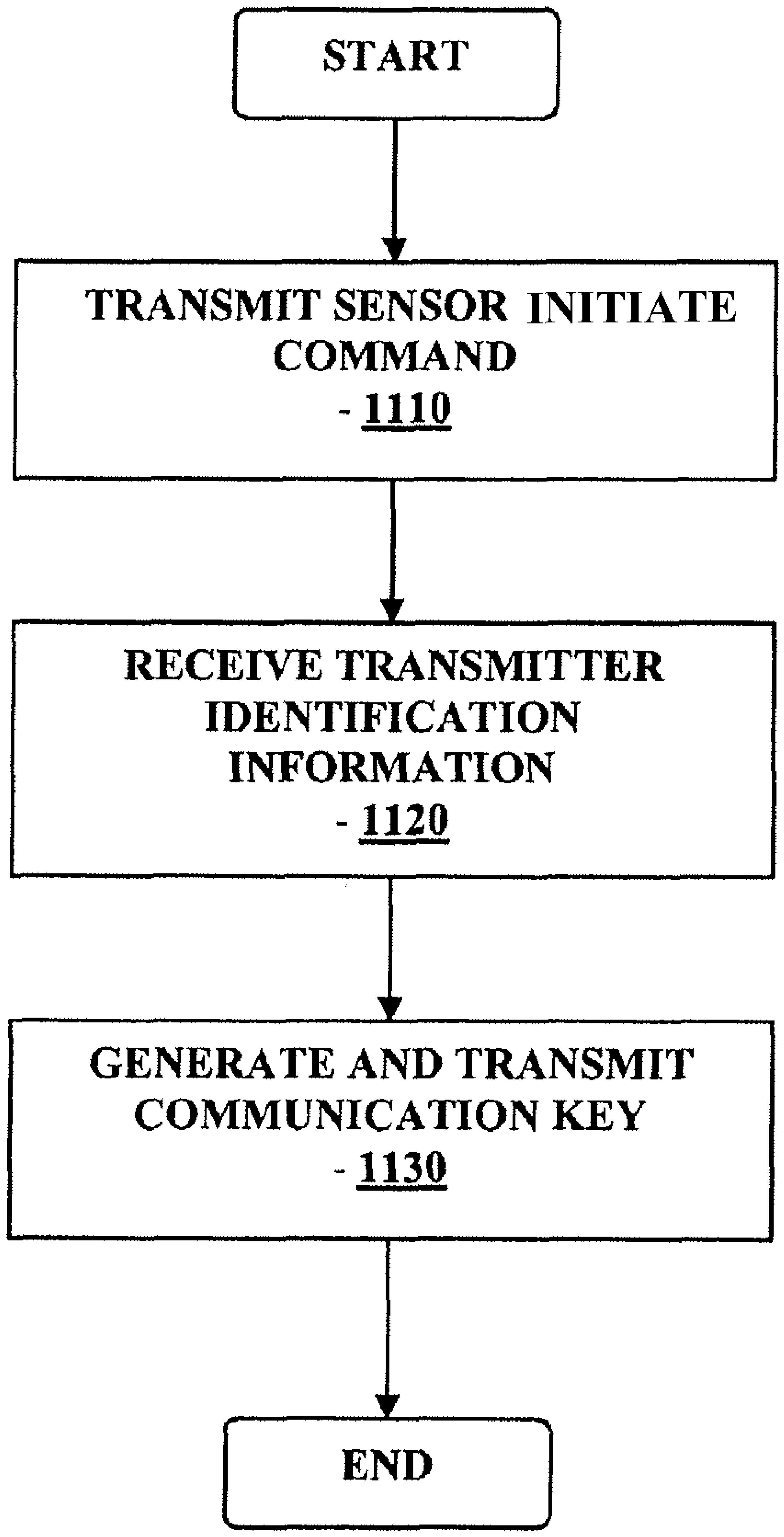

START
TRANSMIT SENSOR INITIATE COMMAND
- 1110
RECEIVE TRANSMITTER IDENTIFICATION INFORMATION
- 1120
GENERATE AND TRANSMIT COMMUNICATION KEY
- 1130
END

FIGURE 11

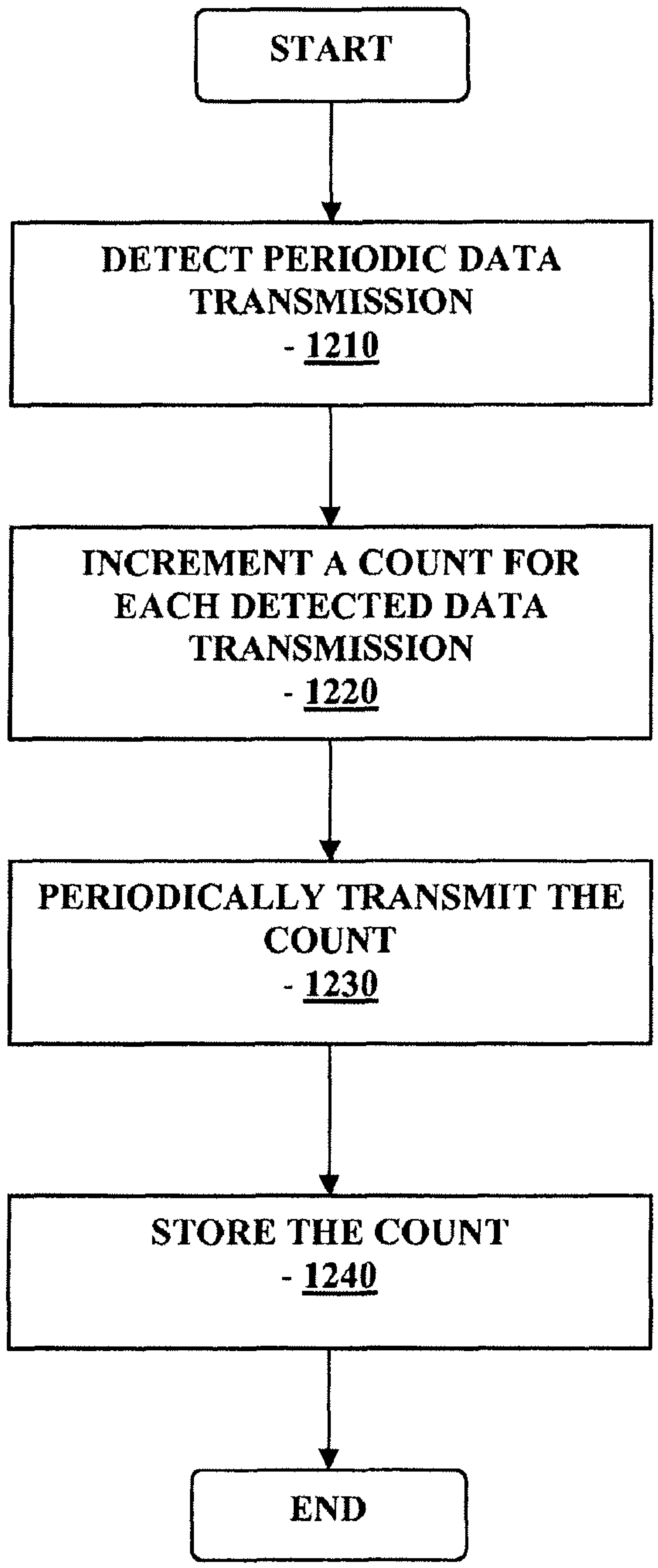

START
DETECT PERIODIC DATA TRANSMISSION - 1210
INCREMENT A COUNT FOR EACH DETECTED DATA TRANSMISSION - 1220
PERIODICALLY TRANSMIT THE COUNT - 1230
STORE THE COUNT - 1240
END

FIGURE 12

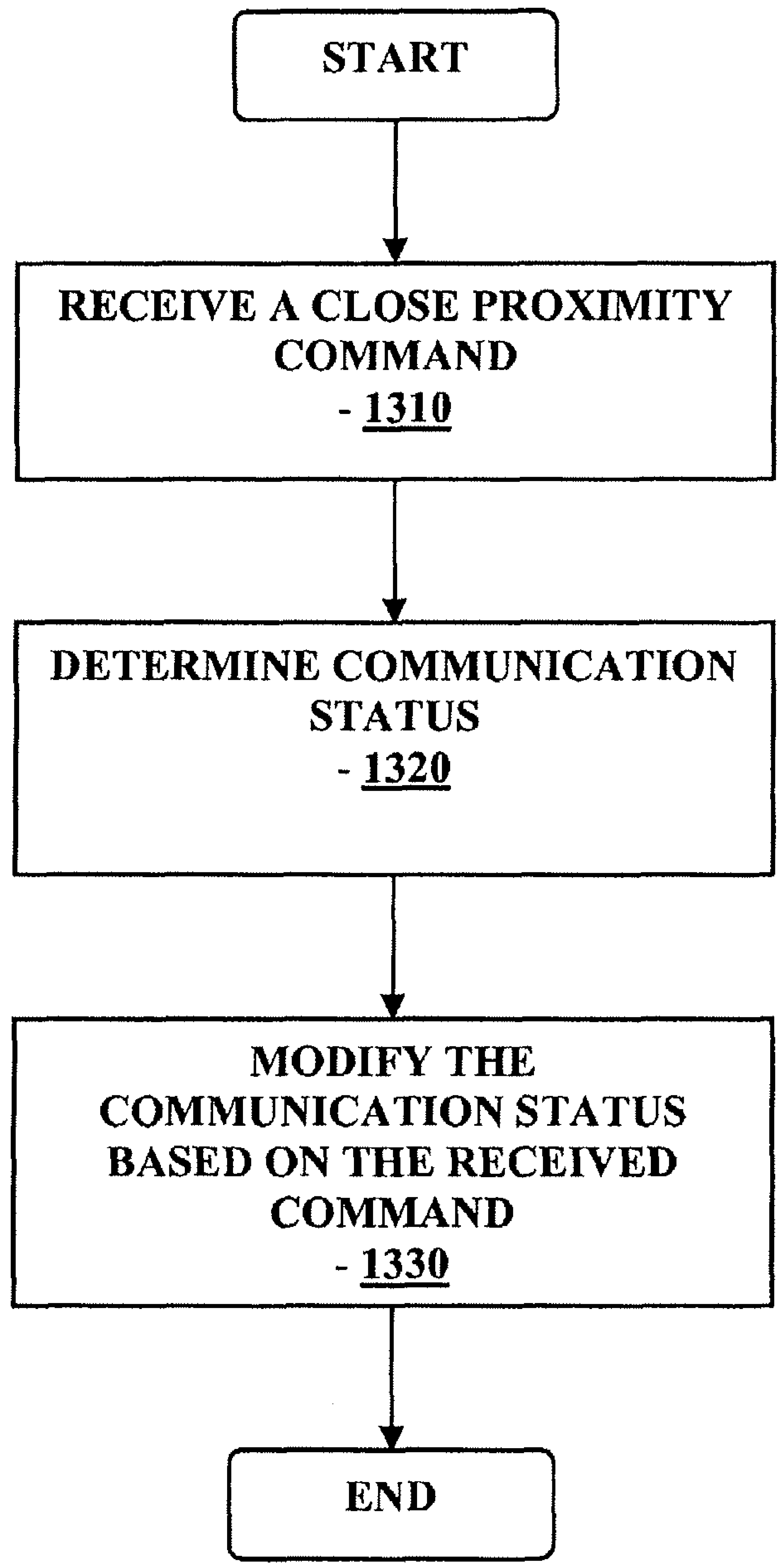

START
RECEIVE A CLOSE PROXIMITY COMMAND
- 1310
DETERMINE COMMUNICATION STATUS
- 1320
MODIFY THE COMMUNICATION STATUS BASED ON THE RECEIVED COMMAND
- 1330
END

FIGURE 13

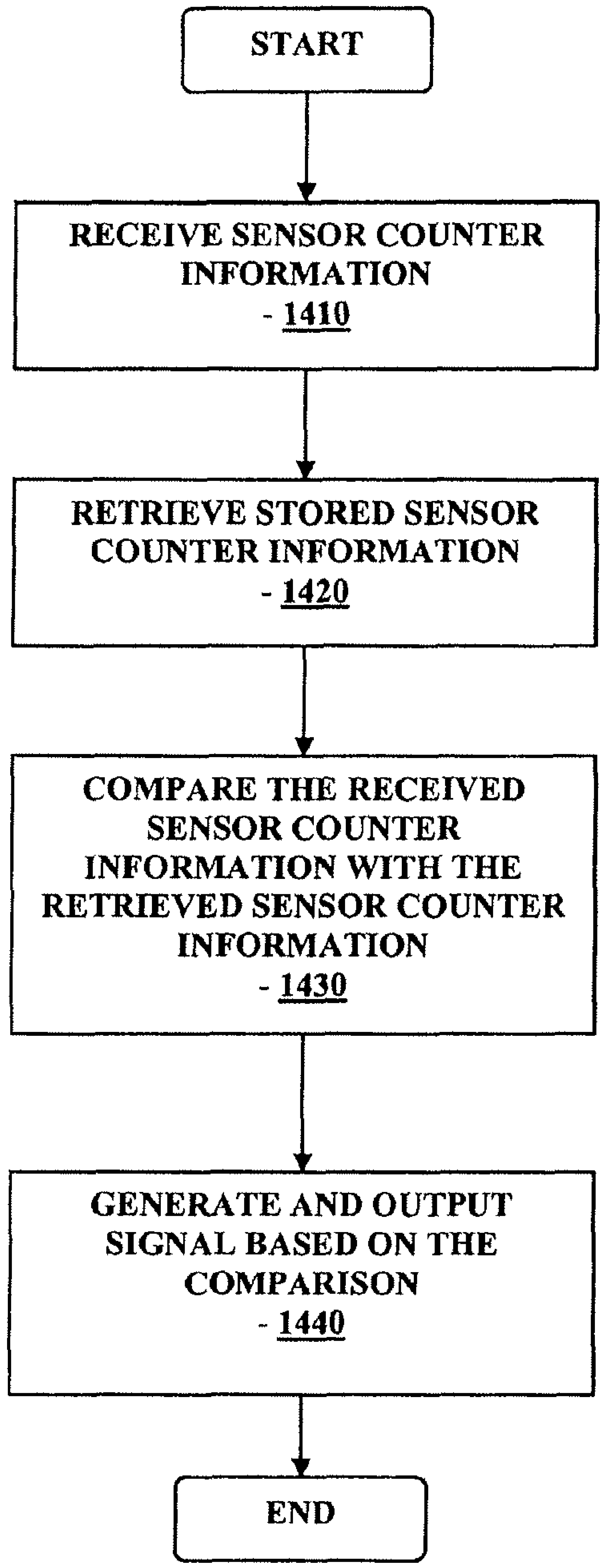

START
RECEIVE SENSOR COUNTER INFORMATION - 1410
RETRIEVE STORED SENSOR COUNTER INFORMATION - 1420
COMPARE THE RECEIVED SENSOR COUNTER INFORMATION WITH THE RETRIEVED SENSOR COUNTER INFORMATION - 1430
GENERATE AND OUTPUT SIGNAL BASED ON THE COMPARISON - 1440
END

FIGURE 14

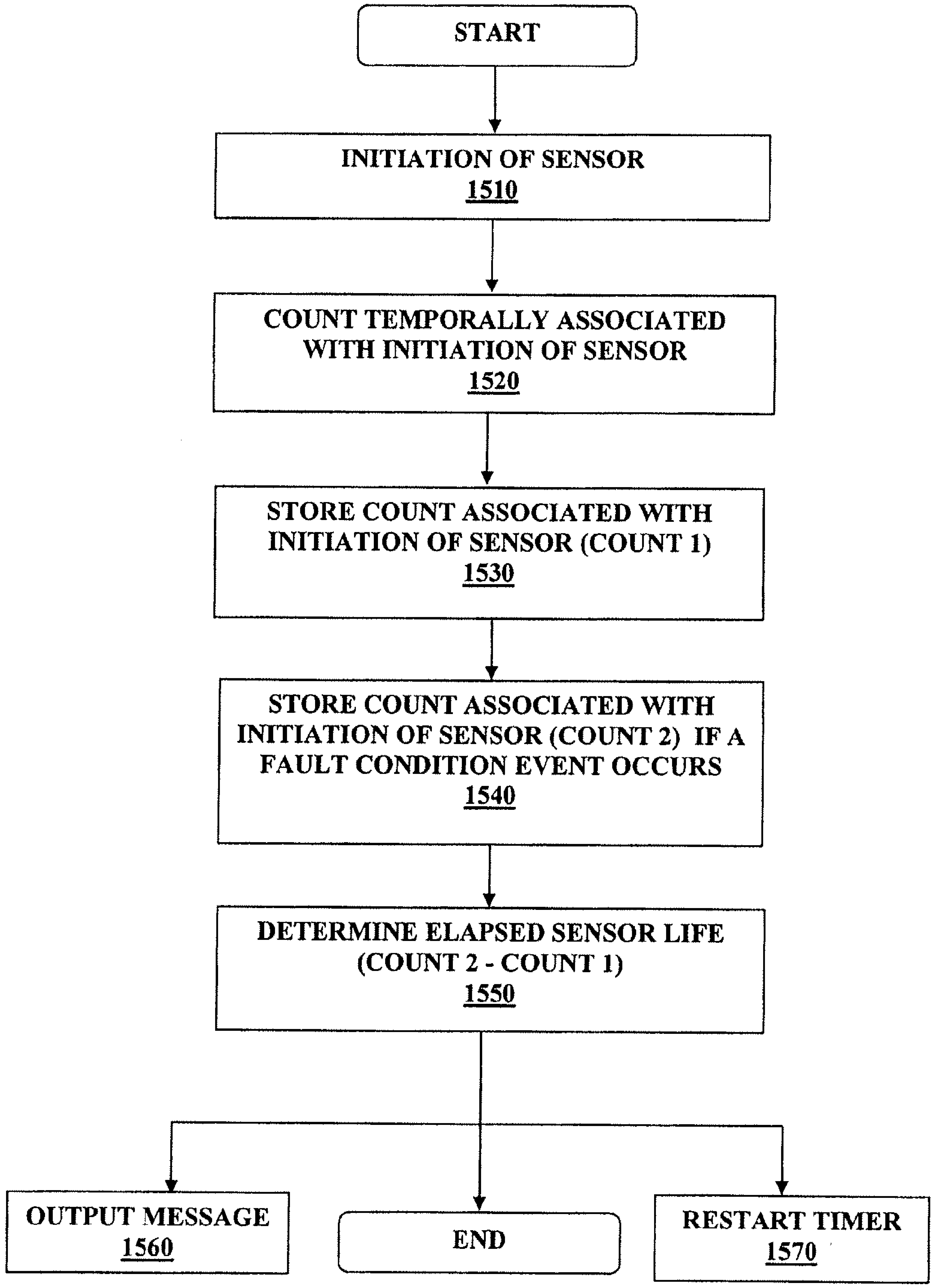

START
INITIATION OF SENSOR
1510
COUNT TEMPORALLY ASSOCIATED WITH INITIATION OF SENSOR
1520
STORE COUNT ASSOCIATED WITH INITIATION OF SENSOR (COUNT 1)
1530
STORE COUNT ASSOCIATED WITH INITIATION OF SENSOR (COUNT 2) IF A FAULT CONDITION EVENT OCCURS
1540
DETERMINE ELAPSED SENSOR LIFE (COUNT 2 - COUNT 1)
1550
OUTPUT MESSAGE
1560
END
RESTART TIMER
1570

FIGURE 15

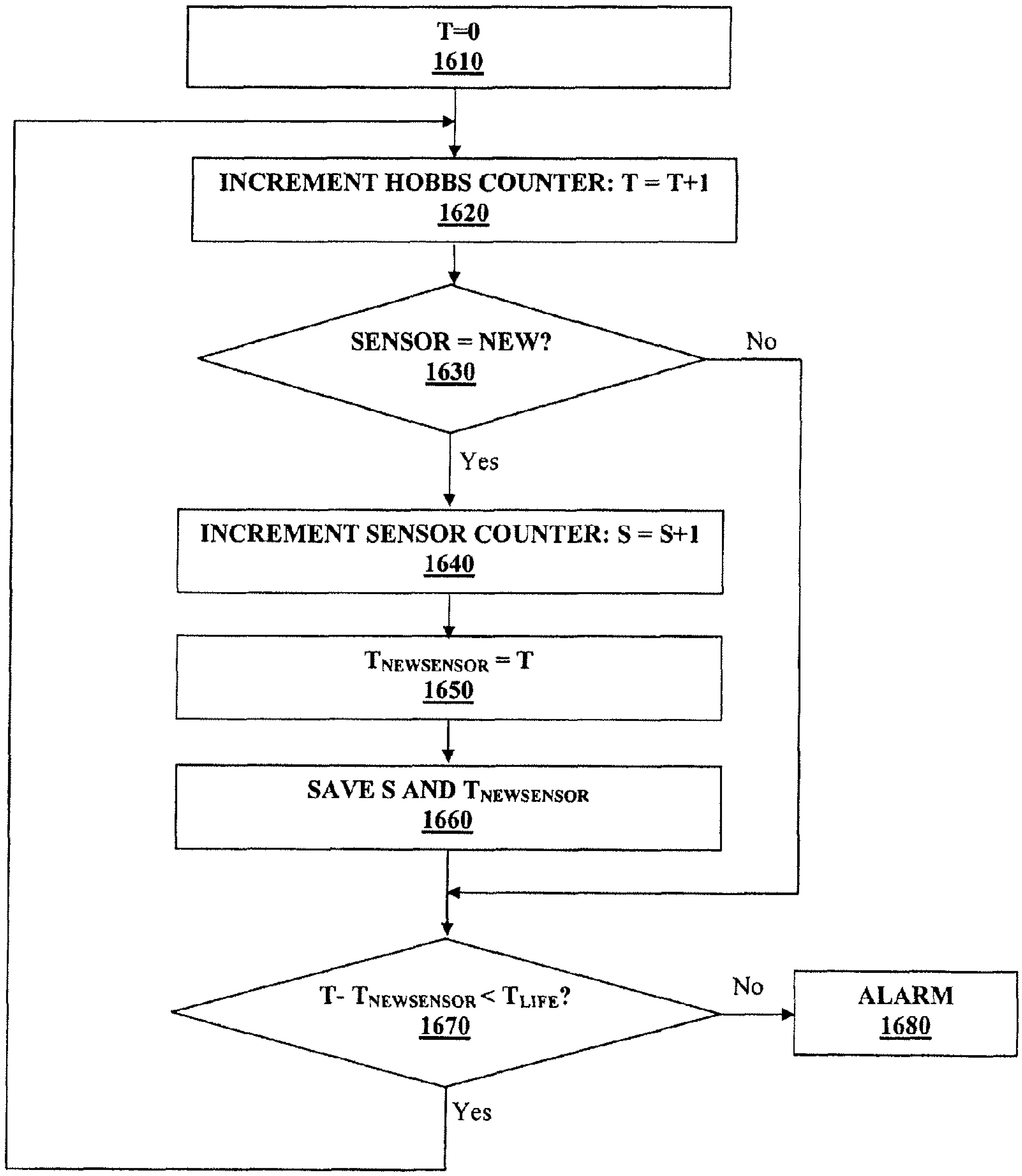

T=0
1610
INCREMENT HOBBS COUNTER: T = T+1
1620
SENSOR = NEW?
1630
No
Yes
INCREMENT SENSOR COUNTER: S = S+1
1640
TNEWSENSOR = T
1650
SAVE S AND TNEWSENSOR
1660
T- TNEWSENSOR < TLIFE?
1670
No
ALARM
1680
Yes

FIGURE 16

# METHOD AND DEVICE FOR DETERMINING ELAPSED SENSOR LIFE

## RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 12/495,219 filed Jun. 30, 2009, now U.S. Pat. No. 8,665,091, which is a continuation-in-part application of U.S. patent application Ser. No. 12/117,681, filed May 8, 2008, now U.S. Pat. No. 8,461,985, entitled "Analyte Monitoring System and Methods," which claims priority under 35 U.S.C. §119(e) to U.S. provisional application No. 60/916,744 filed May 8, 2007, entitled "Analyte Monitoring System and Methods", the disclosures of each of which are incorporated herein by reference for all purposes.

## BACKGROUND

The potential for severe complications caused by persistent high analyte levels and analyte fluctuations has provided the impetus to develop data monitoring and management systems. In this regard, attempts have been made to detect and monitor certain analyte levels, e.g., glucose, with the use of analyte monitoring systems designed to continuously or semi-continuously monitor analyte data from a subject. The analyte monitoring systems often include a sensor configured to detect analyte levels and generate signals corresponding to the detected analyte signals. In some analyte monitoring systems, the sensor is inserted in the body of the subject. Typically, such sensors have a sensor life of about a week. Thus, the sensor must be replaced periodically for continuous analyte detection and monitoring.

Occasionally, data monitoring systems undergo a fault condition, such as for example a power loss, power shutdown, Watchdog reset, or various other system or component failures. During these fault conditions, the system often loses data and time so there is no way for the system to recognize the amount of time elapsed during the fault condition. Thus, after fault conditions, it was necessary for the user to replace the sensor even if the fault condition occurred on day 2 of a 5-day or a 7-day sensor. In addition to the financial costs of replacing a sensor that had remaining life expectancy, the new sensor must be calibrated, requiring multiple finger sticks of the user and time. In view of the foregoing, it would be desirable to have a method and apparatus for determining the elapsed sensor life and/or remaining sensor life subsequent to a fault condition in a medical communication system, so that the same sensor can be used after the fault condition.

## SUMMARY

The purpose and advantages of the present invention will be set forth in and apparent from the description that follows, as well as will be learned by practice of the invention. Additional advantages of the invention will be realized and attained by the methods and systems particularly pointed out in the written description and claims hereof, as well as from the appended drawings.

To achieve these and other advantages and in accordance with the purpose of the invention, as embodied herein and broadly described, the invention includes devices and methods for analyte monitoring, for example but not limited to, glucose monitoring. In accordance with one aspect of the invention, a method is provided for operating an analyte monitoring system. The method includes providing a signal associated with initiation of an analyte sensor and providing



a count from an incrementing counter. The method further includes storing a count that is temporally associated with the signal associated with initiation of the analyte sensor. In one embodiment, initiation of the sensor and signal occurs after placement of the sensor, e.g., transcutaneous implantation or insertion of the sensor to a user. In this regard, the first count commensurate with sensor initiation is saved, for example, in a memory unit, such as a non-volatile memory. After the first count is stored, the counter continues to incrementally count. The incremental count can be based on a periodic cycle associated with calculation of an analyte measurement by the analyte sensor. The periodic cycle can be based on a time interval, e.g., every 30 or 60 seconds, and/or provided in data packets. The periodic calculations of analyte can be transmitted via the data packets to a receiver or transceiver, as rolling data every period.

In accordance with the invention, the method provides a way to determine elapsed (or remaining) sensor life for a particular sensor, for example, by a comparison between the stored first count and the incremental count based on periodic cycles. Further, the elapsed time can be used to restart a sensor life timer and/or calibration timer, if desired.

In a further aspect of the invention, a second signal can be provided, wherein the second signal temporally associated with a second initiation of an analyte is stored, if a fault conditions occurs. In this regard, the elapsed time of the sensor can be determined by a comparison of the stored counts for the first and second signals that are temporally associated with initiation of the sensor and re-initiation of the sensor after the occurrence of a fault condition. For example, but not limitation, a system failure includes a battery drain, power shut-down (voluntary or involuntary), system reset.

In another aspect of the invention, the method includes providing a second counter that incrementally counts each time a new sensor is initialized. Thus, the method includes a first counter that incrementally counts and a second counter that only incrementally counts when a sensor is initialized. In this regard, the second counter can provide information regarding how many sensors have been employed (or initialized) in the data monitoring system.

In one embodiment, the second counter can be used in conjunction with the first counter to determine the elapsed time for a particular sensor. In this regard, the incremental count of the first counter, such as a Hobbs counter provides an indication of time duration, while the second counter, such as a sensor counter, can provide information regarding the occurrence of sensor initiation. In this regard, the count of the Hobbs counter is saved when the sensor counter indicates initiation of a sensor. Thus, the two counters, i.e., a comparison of information derived from both the first counter and the second counter, can be used to determine the elapsed time of an employed sensor.

In another aspect of the invention, a data processing device configured to determine elapsed life of a sensor is provided. The data processing device includes a data processing section coupled to a data communication unit and at least one counter, e.g., Hobbs counter. In accordance with one aspect of the invention, the elapsed life of a sensor is determined by comparing the stored count with the incremented count. In another embodiment, the data processing device includes two counters, e.g., a Hobbs counter and a sensor counter. Elapsed life can be determined by comparing the counts of both counters in conjunction with each other.

The data processing device can further include a storage unit such as a non-volatile memory unit to store the count. The non-volatile memory unit can be disposed in a transmitter or a receiver unit. Further, the data processing device can include an output unit for outputting a message, such as date and time of sensor expiration, data and time for next calibration, or a value derived from the count information, such as remaining life of the sensor. A method further includes displaying a value derived or otherwise associated with the stored count, and/or the incremented count on a display unit. Further, the output unit can be configured to display an alarm when a calibration is needed, and/or when the sensor is close to expiration. The output unit includes one or more of a visual, audible or tactile output. In accordance with one embodiment, the display unit can be a receiver or, if desired, a transmitter. In one embodiment, the display is an OLED color display.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and are intended to provide further explanation of the invention claimed. The accompanying drawings are included to illustrate and provide a further understanding of the method and device of the invention. Together with the description, the drawings serve to explain the principles of the invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a block diagram of a data monitoring and management system for practicing one or more embodiments of the present invention;

FIG. **2** is a block diagram of the transmitter unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention;

FIG. **3** is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention;

FIG. **4** is a flowchart illustrating data packet procedure including rolling data for transmission in accordance with one embodiment of the present invention;

FIG. **5** is a flowchart illustrating data processing of the received data packet including the rolling data in accordance with one embodiment of the present invention;

FIG. **6** is a block diagram illustrating the sensor and the transmitter unit of the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention;

FIG. **7** is a flowchart illustrating data communication using close proximity commands in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention;

FIG. **8** is a flowchart illustrating sensor insertion detection routine in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention;

FIG. **9** is a flowchart illustrating sensor removal detection routine in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention;

FIG. **10** is a flowchart illustrating the pairing or synchronization routine in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention;

FIG. **11** is a flowchart illustrating the pairing or synchronization routine in the data monitoring and management system of FIG. **1** in accordance with another embodiment of the present invention;

FIG. **12** is a flowchart illustrating the power supply determination in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention;

FIG. **13** is a flowchart illustrating close proximity command for RF communication control in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention;

FIG. **14** is a flowchart illustrating analyte sensor identification routine in accordance with one embodiment of the present invention;

FIG. **15** is a flowchart illustrating the analyte sensor life determination in accordance with one embodiment of the present invention; and

FIG. **16** is a flowchart illustrating the analyte sensor life determination in accordance with one embodiment of the present invention.

## DETAILED DESCRIPTION

As summarized above and as described in further detail below, in accordance with various embodiments of the invention, there are provided a method and system for operating an analyte monitoring device.

FIG. **1** illustrates a data monitoring and management system such as, for example, analyte (e.g., glucose) monitoring system **100** in accordance with one embodiment of the present invention. The subject invention is further described primarily with respect to a glucose monitoring system for convenience and such description is in no way intended to limit the scope of the invention. It is to be understood that the analyte monitoring system may be configured to monitor a variety of analytes, e.g., lactate, and the like. Analytes that may be monitored include, for example, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be monitored. More than one analyte may be monitored by a single system, e.g. a single analyte sensor.

The analyte monitoring system **100** includes a sensor **101**, a transmitter unit **102** coupleable to the sensor **101**, and a primary receiver unit **104** which is configured to communicate with the transmitter unit **102** via a bi-directional communication link **103**. The primary receiver unit **104** may be further configured to transmit data to a data processing terminal **105** for evaluating the data received by the primary receiver unit **104**. Moreover, the data processing terminal **105** in one embodiment may be configured to receive data directly from the transmitter unit **102** via a communication link which may optionally be configured for bi-directional communication. Accordingly, transmitter unit **102** and/or receiver unit **104** may include a transceiver.

Also shown in FIG. **1** is an optional secondary receiver unit **106** which is operatively coupled to the communication link and configured to receive data transmitted from the transmitter unit **102**. Moreover, as shown in the Figure, the secondary receiver unit **106** is configured to communicate with the primary receiver unit **104** as well as the data processing terminal **105**. Indeed, the secondary receiver unit **106** may be configured for bidirectional wireless communication with each or one of the primary receiver unit **104** and the data processing terminal **105**. As discussed in further detail below, in one embodiment of the present invention, the secondary receiver unit **106** may be configured to include a limited number of functions and features as compared with the primary receiver unit **104**. As such, the secondary receiver unit **106** may be configured substantially in a smaller compact housing or embodied in a device such as a wrist watch, pager, mobile phone, PDA, for example. Alternatively, the secondary receiver unit **106** may be configured with the same or substantially similar functionality as the primary receiver unit **104**. The receiver unit may be configured to be used in conjunction with a docking cradle unit, for example for one or more of the following or other functions: placement by bedside, for re-charging, for data management, for night time monitoring, and/or bidirectional communication device.

In one aspect, sensor **101** may include two or more sensors, each configured to communicate with transmitter unit **102**. Furthermore, while only one transmitter unit **102**, communication link **103**, and data processing terminal **105** are shown in the embodiment of the analyte monitoring system **100** illustrated in FIG. **1**, it will be appreciated by one of ordinary skill in the art that the analyte monitoring system **100** may include one or more sensors, multiple transmitter units **102**, communication links **103**, and data processing terminals **105**. Moreover, within the scope of the present invention, the analyte monitoring system **100** may be a continuous monitoring system, or semi-continuous, or a discrete monitoring system. In a multi-component environment, each device is configured to be uniquely identified by each of the other devices in the system so that communication conflict is readily resolved between the various components within the analyte monitoring system **100**.

In one embodiment of the present invention, the sensor **101** is physically positioned in or on the body of a user whose analyte level is being monitored. The sensor **101** may be configured to continuously sample the analyte level of the user and convert the sampled analyte level into a corresponding data signal for transmission by the transmitter unit **102**. In certain embodiments, the transmitter unit **102** may be physically coupled to the sensor **101** so that both devices are integrated in a single housing and positioned on the user's body. The transmitter unit **102** may perform data processing such as filtering and encoding on data signals and/or other functions, each of which corresponds to a sampled analyte level of the user, and in any event transmitter unit **102** transmits analyte information to the primary receiver unit **104** via the communication link **103**.

In one embodiment, the analyte monitoring system **100** is configured as a one-way RF communication path from the transmitter unit **102** to the primary receiver unit **104**. In such embodiment, the transmitter unit **102** transmits the sampled data signals received from the sensor **101** without acknowledgement from the primary receiver unit **104** that the transmitted sampled data signals have been received. For example, the transmitter unit **102** may be configured to transmit the encoded sampled data signals at a fixed rate (e.g., at one minute intervals) after the completion of the initial power on procedure. Likewise, the primary receiver unit **104** may be configured to detect such transmitted encoded sampled data signals at predetermined time intervals. Alternatively, the analyte monitoring system **100** may be configured with a bi-directional RF (or otherwise) communication between the transmitter unit **102** and the primary receiver unit **104**.

Additionally, in one aspect, the primary receiver unit **104** may include two sections. The first section is an analog interface section that is configured to communicate with the transmitter unit **102** via the communication link **103**. In one embodiment, the analog interface section may include an RF receiver and an antenna for receiving and amplifying the data signals from the transmitter unit **102**, which are thereafter, demodulated with a local oscillator and filtered through a band-pass filter. The second section of the primary receiver unit **104** is a data processing section which is configured to process the data signals received from the transmitter unit **102** such as by performing data decoding, error detection and correction, data clock generation, and data bit recovery.

In operation, upon completing the power-on procedure, the primary receiver unit **104** is configured to detect the presence of the transmitter unit **102** within its range based on, for example, the strength of the detected data signals received from the transmitter unit **102** and/or predetermined transmitter identification information. Upon successful synchronization with the corresponding transmitter unit **102**, the primary receiver unit **104** is configured to begin receiving from the transmitter unit **102** data signals corresponding to the user's detected analyte level. More specifically, the primary receiver unit **104** in one embodiment is configured to perform synchronized time hopping with the corresponding synchronized transmitter unit **102** via the communication link **103** to obtain the user's detected analyte level.

Referring again to FIG. **1**, the data processing terminal **105** may include a personal computer, a portable computer such as a laptop or a handheld device (e.g., personal digital assistants (PDAs)), and the like, each of which may be configured for data communication with the receiver via a wired or a wireless connection. Additionally, the data processing terminal **105** may further be connected to a data network (not shown) for storing, retrieving and updating data corresponding to the detected analyte level of the user.

Within the scope of the present invention, the data processing terminal **105** may include an infusion device such as an insulin infusion pump (external or implantable) or the like, which may be configured to administer insulin to patients, and which may be configured to communicate with the receiver unit **104** for receiving, among others, the measured analyte level. Alternatively, the receiver unit **104** may be configured to integrate or otherwise couple to an infusion device therein so that the receiver unit **104** is configured to administer insulin therapy to patients, for example, for administering and modifying basal profiles, as well as for determining appropriate boluses for administration based on, among others, the detected analyte levels received from the transmitter unit **102**.

Additionally, the transmitter unit **102**, the primary receiver unit **104** and the data processing terminal **105** may each be configured for bidirectional wireless communication such that each of the transmitter unit **102**, the primary receiver unit **104** and the data processing terminal **105** may be configured to communicate (that is, transmit data to and receive data from) with each other via the wireless communication link **103**. More specifically, the data processing terminal **105** may in one embodiment be configured to receive data directly from the transmitter unit **102** via a communication link, where the communication link, as described above, may be configured for bi-directional communication.

In this embodiment, the data processing terminal **105** which may include an insulin pump, may be configured to receive the analyte signals from the transmitter unit **102**, and thus, incorporate the functions of the receiver unit **104** including data processing for managing the patient's insulin therapy and analyte monitoring. In one embodiment, the communication link **103** may include one or more of an RF communication protocol, an infrared communication protocol, a Bluetooth® enabled communication protocol, an 802.11x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPAA requirements) while avoiding potential data collision and interference.

FIG. **2** is a block diagram of the transmitter of the data monitoring and detection system shown in FIG. **1** in accordance with one embodiment of the present invention. Referring to the Figure, the transmitter unit **102** in one embodiment includes an analog interface **201** configured to communicate with the sensor **101** (FIG. **1**), a user input **202**, and a temperature detection section **203**, each of which is operatively coupled to a transmitter processor **204** such as a central processing unit (CPU). As can be seen from FIG. **2**, there are provided four contacts, three of which are electrodes—work electrode (W) **210**, guard contact (G) **211**, reference electrode (R) **212**, and counter electrode (C) **213**, each operatively coupled to the analog interface **201** of the transmitter unit **102** for connection to the sensor **101** (FIG. **1**). In one embodiment, each of the work electrode (W) **210**, guard contact (G) **211**, reference electrode (R) **212**, and counter electrode (C) **213** may be made using a conductive material that is either printed or etched or ablated, for example, such as carbon which may be printed, or a metal such as a metal foil (e.g., gold) or the like, which may be etched or ablated or otherwise processed to provide one or more electrodes. Fewer or greater electrodes and/or contact may be provided in certain embodiments.

Further shown in FIG. **2** are a transmitter serial communication section **205** and an RF transmitter **206**, each of which is also operatively coupled to the transmitter processor **204**. Moreover, a power supply **207** such as a battery is also provided in the transmitter unit **102** to provide the necessary power for the transmitter unit **102**.

Additionally, as can be seen from the Figure, clock **208** is provided to, among others, supply real time information to the transmitter processor **204**.

In one embodiment, a unidirectional input path is established from the sensor **101** (FIG. **1**) and/or manufacturing and testing equipment to the analog interface **201** of the transmitter unit **102**, while a unidirectional output is established from the output of the RF transmitter **206** of the transmitter unit **102** for transmission to the primary receiver unit **104**. In this manner, a data path is shown in FIG. **2** between the aforementioned unidirectional input and output via a dedicated link **209** from the analog interface **201** to serial communication section **205**, thereafter to the processor **204**, and then to the RF transmitter **206**. As such, in one embodiment, via the data path described above, the transmitter unit **102** is configured to transmit to the primary receiver unit **104** (FIG. **1**), via the communication link **103** (FIG. **1**), processed and encoded data signals received from the sensor **101** (FIG. **1**). Additionally, the unidirectional communication data path between the analog interface **201** and the RF transmitter **206** discussed above allows for the configuration of the transmitter unit **102** for operation upon completion of the manufacturing process as well as for direct communication for diagnostic and testing purposes.

As discussed above, the transmitter processor **204** is configured to transmit control signals to the various sections of the transmitter unit **102** during the operation of the transmitter unit **102**. In one embodiment, the transmitter processor **204** also includes a memory (not shown) for storing data such as the identification information for the transmitter unit **102**, as well as the data signals received from the sensor **101**. The stored information may be retrieved and processed for transmission to the primary receiver unit **104** under the control of the transmitter processor **204**. Furthermore, the power supply **207** may include a commercially available battery, which may be a rechargeable battery.

In certain embodiments, the transmitter unit **102** is also configured such that the power supply section **207** is capable of providing power to the transmitter for a minimum of about three months of continuous operation, e.g., after having been stored for about eighteen months such as stored in a low-power (non-operating) mode. In one embodiment, this may be achieved by the transmitter processor **204** operating in low power modes in the non-operating state, for example, drawing no more than approximately 1 μA of current. Indeed, in one embodiment, a step during the manufacturing process of the transmitter unit **102** may place the transmitter unit **102** in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the transmitter unit **102** may be significantly improved. Moreover, as shown in FIG. **2**, while the power supply unit **207** is shown as coupled to the processor **204**, and as such, the processor **204** is configured to provide control of the power supply unit **207**, it should be noted that within the scope of the present invention, the power supply unit **207** is configured to provide the necessary power to each of the components of the transmitter unit **102** shown in FIG. **2**.

Referring back to FIG. **2**, the power supply section **207** of the transmitter unit **102** in one embodiment may include a rechargeable battery unit that may be recharged by a separate power supply recharging unit (for example, provided in the receiver unit **104**) so that the transmitter unit **102** may be powered for a longer period of usage time. Moreover, in one embodiment, the transmitter unit **102** may be configured without a battery in the power supply section **207**, in which case the transmitter unit **102** may be configured to receive power from an external power supply source (for example, a battery) as discussed in further detail below.

Referring yet again to FIG. **2**, the temperature detection section **203** of the transmitter unit **102** is configured to monitor the temperature of the skin near the sensor insertion site. The temperature reading is used to adjust the analyte readings obtained from the analog interface **201**. In certain embodiments, the RF transmitter **206** of the transmitter unit **102** may be configured for operation in the frequency band of approximately 315 MHz to approximately 322 MHz, for example, in the United States. In certain embodiments, the RF transmitter **206** of the transmitter unit **102** may be configured for operation in the frequency band of approximately 400 MHz to approximately 470 MHz. Further, in one embodiment, the RF transmitter **206** is configured to modulate the carrier frequency by performing Frequency Shift Keying and Manchester encoding. In one embodiment, the data transmission rate is about 19,200 symbols per second, with a minimum transmission range for communication with the primary receiver unit **104**.

Referring yet again to FIG. **2**, also shown is a leak detection circuit **214** coupled to the guard contact (G) **211** and the processor **204** in the transmitter unit **102** of the data monitoring and management system **100**. The leak detection circuit **214** in accordance with one embodiment of the present invention may be configured to detect leakage current in the sensor **101** to determine whether the measured sensor data are corrupt or whether the measured data from the sensor **101** is accurate. Exemplary analyte systems that may be employed are described in, for example, U.S. Pat. Nos. 6,134,461, 6,175,752, 6,121,611, 6,560,471, 6,746, 582, and elsewhere, the disclosure of each of which are incorporated by reference for all purposes.

FIG. **3** is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention. Referring to FIG. **3**, the primary receiver unit **104** includes an analyte test strip, e.g., blood glucose test strip, interface **301**, an RF receiver **302**, an input **303**, a temperature detection section **304**, and a clock **305**, each of which is operatively coupled to a receiver processor **307**. As can be further seen from the Figure, the primary receiver unit **104** also includes a power supply **306** operatively coupled to a power conversion and monitoring section **308**. Further, the power conversion and monitoring section **308** is also coupled to the receiver processor **307**. Moreover, also shown are a receiver serial communication section **309**, and an output **310**, each operatively coupled to the receiver processor **307**.

In one embodiment, the test strip interface **301** includes a glucose level testing portion to receive a manual insertion of a glucose test strip, and thereby determine and display the glucose level of the test strip on the output **310** of the primary receiver unit **104**. This manual testing of glucose may be used to calibrate the sensor **101** or otherwise. The RF receiver **302** is configured to communicate, via the communication link **103** (FIG. **1**) with the RF transmitter **206** of the transmitter unit **102**, to receive encoded data signals from the transmitter unit **102** for, among others, signal mixing, demodulation, and other data processing. The input **303** of the primary receiver unit **104** is configured to allow the user to enter information into the primary receiver unit **104** as needed. In one aspect, the input **303** may include one or more keys of a keypad, a touch-sensitive screen, or a voice-activated input command unit. The temperature detection section **304** is configured to provide temperature information of the primary receiver unit **104** to the receiver processor **307**, while the clock **305** provides, among others, real time information to the receiver processor **307**.

Each of the various components of the primary receiver unit **104** shown in FIG. **3** is powered by the power supply **306** which, in one embodiment, includes a battery. Furthermore, the power conversion and monitoring section **308** is configured to monitor the power usage by the various components in the primary receiver unit **104** for effective power management and to alert the user, for example, in the event of power usage which renders the primary receiver unit **104** in sub-optimal operating conditions. An example of such sub-optimal operating condition may include, for example, operating the vibration output mode (as discussed below) for a period of time thus substantially draining the power supply **306** while the processor **307** (thus, the primary receiver unit **104**) is turned on. Moreover, the power conversion and monitoring section **308** may additionally be configured to include a reverse polarity protection circuit such as a field effect transistor (FET) configured as a battery activated switch.

The serial communication section **309** in the primary receiver unit **104** is configured to provide a bi-directional communication path from the testing and/or manufacturing equipment for, among others, initialization, testing, and configuration of the primary receiver unit **104**. Serial communication section **309** can also be used to upload data to a computer, such as time-stamped blood glucose data. The communication link with an external device (not shown) can be made, for example, by cable, infrared (IR) or RF link. The output **310** of the primary receiver unit **104** is configured to provide, among others, a graphical user interface (GUI) such as a liquid crystal display (LCD) for displaying information. Additionally, the output **310** may also include an integrated speaker for outputting audible signals as well as to provide vibration output as commonly found in handheld electronic devices, such as mobile telephones presently available. In a further embodiment, the primary receiver unit **104** also includes an electro-luminescent lamp configured to provide backlighting to the output **310** for output visual display in dark ambient surroundings.

Referring back to FIG. **3**, the primary receiver unit **104** in one embodiment may also include a storage section such as a programmable, non-volatile memory device as part of the processor **307**, or provided separately in the primary receiver unit **104**, operatively coupled to the processor **307**. The processor **307** may be configured to synchronize with a transmitter, e.g., using Manchester decoding or the like, as well as error detection and correction upon the encoded data signals received from the transmitter unit **102** via the communication link **103**.

Additional description of the RF communication between the transmitter unit **102** and the primary receiver unit **104** (or with the secondary receiver unit **106**) that may be employed in embodiments of the subject invention is disclosed in .U.S. patent application Ser. No. 11/060,365 filed Feb. 16, 2005, now U.S. Pat. No. 8,771,183 entitled "Method and System for Providing Data Communication in Continuous Glucose Monitoring and Management System" the disclosure of which is incorporated herein by reference for all purposes.

Referring to the Figures, in one embodiment, the transmitter unit **102** (FIG. **1**) may be configured to generate data packets for periodic transmission to one or more of the receiver units **104**, **106**, where each data packet includes in one embodiment two categories of data—urgent data and non-urgent data. For example, urgent data such as for example glucose data from the sensor and/or temperature data associated with the sensor may be packed in each data packet in addition to non-urgent data, where the non-urgent data is rolled or varied with each data packet transmission.

That is, the non-urgent data is transmitted at a timed interval so as to maintain the integrity of the analyte monitoring system without being transmitted over the RF communication link with each data transmission packet from the transmitter unit **102**. In this manner, the non-urgent data, for example that are not time sensitive, may be periodically transmitted (and not with each data packet transmission) or broken up into predetermined number of segments and sent or transmitted over multiple packets, while the urgent data is transmitted substantially in its entirety with each data transmission.

Referring again to the Figures, upon receiving the data packets from the transmitter unit **102**, the one or more receiver units **104**, **106** may be configured to parse the received data packet to separate the urgent data from the non-urgent data, and also, may be configured to store the urgent data and the non-urgent data, e.g., in a hierarchical manner. In accordance with the particular configuration of the data packet or the data transmission protocol, more or less data may be transmitted as part of the urgent data, or the non-urgent rolling data. That is, within the scope of the present disclosure, the specific data packet implementation such as the number of bits per packet, and the like, may vary based on, among others, the communication protocol, data transmission time window, and so on.

In an exemplary embodiment, different types of data packets may be identified accordingly. For example, identification in certain exemplary embodiments may include—(1) single sensor, one minute of data, (2) two or multiple sensors, (3) dual sensor, alternate one minute data, and (4) response packet. For single sensor one minute data packet, in one embodiment, the transmitter unit **102** may be configured to generate the data packet in the manner, or similar to the manner, shown in Table 1 below.

TABLE 1

Single Sensor, One Minute of Data

| Number of Bits | Data Field |
|---|---|
| 8 | Transmit Time |
| 14 | Sensor 1 Current Data |
| 14 | Sensor 1 Historic Data |
| 8 | Transmit Status |
| 12 | AUX Counter |
| 12 | AUX Thermistor 1 |
| 12 | AUX Thermistor 2 |
| 8 | Rolling-Data-1 |

As shown in Table 1 above, the transmitter data packet in one embodiment may include 8 bits of transmit time data, 14 bits of current sensor data, 14 bits of preceding sensor data, 8 bits of transmitter status data, 12 bits of auxiliary counter data, 12 bits of auxiliary thermistor 1 data, 12 bits of auxiliary thermistor 1 data and 8 bits of rolling data. In one embodiment of the present invention, the data packet generated by the transmitter for transmission over the RF communication link may include all or some of the data shown above in Table 1.

Referring back, the 14 bits of the current sensor data provides the real time or current sensor data associated with the detected analyte level, while the 14 bits of the sensor historic or preceding sensor data includes the sensor data associated with the detected analyte level one minute ago. In this manner, in the case where the receiver unit **104**, **106** drops or fails to successfully receive the data packet from the transmitter unit **102** in the minute by minute transmission, the receiver unit **104**, **106** may be able to capture the sensor data of a prior minute transmission from a subsequent minute transmission.

Referring again to Table 1, the Auxiliary data in one embodiment may include one or more of the patient's skin temperature data, a temperature gradient data, reference data, and counter electrode voltage. The transmitter status field may include status data that is configured to indicate corrupt data for the current transmission (for example, if shown as BAD status (as opposed to GOOD status which indicates that the data in the current transmission is not corrupt)). Furthermore, the rolling data field is configured to include the non-urgent data, and in one embodiment, may be associated with the time-hop sequence number. In addition, the Transmitter Time field in one embodiment includes a protocol value that is configured to start at zero and is incremented by one with each data packet. In one aspect, the transmitter time data may be used to synchronize the data transmission window with the receiver unit **104**, **106**, and also, provide an index for the Rolling data field.

In a further embodiment, the transmitter data packet may be configured to provide or transmit analyte sensor data from two or more independent analyte sensors. The sensors may relate to the same or different analyte or property. In such a case, the data packet from the transmitter unit **102** may be configured to include 14 bits of the current sensor data from both sensors in the embodiment in which 2 sensors are employed. In this case, the data packet does not include the immediately preceding sensor data in the current data packet transmission. Instead, a second analyte sensor data is transmitted with a first analyte sensor data.

TABLE 2

Dual Sensor Data

| Number of Bits | Data Field |
|---|---|
| 8 | Transmit Time |
| 14 | Sensor 1 Current Data |
| 14 | Sensor 2 Historic Data |
| 8 | Transmit Status |
| 12 | AUX Counter |
| 12 | AUX Thermistor 1 |
| 12 | AUX Thermistor 2 |
| 8 | Rolling-Data-1 |

In a further embodiment, the transmitter data packet may be alternated with each transmission between two analyte sensors, for example, alternating between the data packet shown in Table 3 and Table 4 below.

TABLE 3

Sensor Data Packet Alternate 1

| Number of Bits | Data Field |
|---|---|
| 8 | Transmit Time |
| 14 | Sensor 1 Current Data |
| 14 | Sensor 1 Historic Data |
| 8 | Transmit Status |
| 12 | AUX Counter |
| 12 | AUX Thermistor 1 |
| 12 | AUX Thermistor 2 |
| 8 | Rolling-Data-1 |

TABLE 4

Sensor Data Packet Alternate 2

| Number of Bits | Data Field |
|---|---|
| 8 | Transmit Time |
| 14 | Sensor 1 Current Data |
| 14 | Sensor 2 Historic Data |
| 8 | Transmit Status |
| 12 | AUX Counter |
| 12 | AUX Thermistor 1 |
| 12 | AUX Thermistor 2 |
| 8 | Rolling-Data-1 |

As shown above in reference to Tables 3 and 4, the minute by minute data packet transmission from the transmitter unit **102** (FIG. **1**) in one embodiment may alternate between the data packet shown in Table 3 and the data packet shown in Table 4. More specifically, the transmitter unit **102** may be configured in one embodiment to transmit the current sensor data of the first sensor and the preceding sensor data of the first sensor (Table 3), as well as the rolling data, and further, at the subsequent transmission, the transmitter unit **102** may be configured to transmit the current sensor data of the first and the second sensor in addition to the rolling data (Table 4).

In one embodiment, the rolling data transmitted with each data packet may include a sequence of various predetermined types of data that are considered not-urgent or not time sensitive. That is, in one embodiment, the following list of data shown in Table 5 may be sequentially included in the 8 bits of transmitter data packet, and not transmitted with each data packet transmission of the transmitter (for example, with each 60 second data transmission from the transmitter unit **102**).

TABLE 5

| Rolling Data | | |
|---|---|---|
| Time Slot | Bits | Rolling Data |
| 0 | 8 | Mode |
| 1 | 8 | Glucose 1 Slope |
| 2 | 8 | Glucose 2 Slope |
| 3 | 8 | Ref-R |
| 4 | 8 | Hobbs Counter, Ref-R |
| 5 | 8 | Hobbs Counter |
| 6 | 8 | Hobbs Counter |
| 7 | 8 | Sensor Count |

As can be seen from Table 5 above, in one embodiment, a sequence of rolling data are appended or added to the transmitter data packet with each data transmission time slot. In one embodiment, there may be 256 time slots for data transmission by the transmitter unit **102** (FIG. **1**), and where, each time slot is separated by approximately 60 second interval. For example, referring to the Table 5 above, the data packet in transmission time slot 0 (zero) may include operational mode data (Mode) as the rolling data that is appended to the transmitted data packet. At the subsequent data transmission time slot (for example, approximately 60 seconds after the initial time slot (0)), the transmitted data packet may include the analyte sensor **1** calibration factor information (Glucose 1 slope) as the rolling data. In this manner, with each data transmission, the rolling data may be updated over the 256 time slot cycle.

Referring again to Table 5, each rolling data field is described in further detail for various embodiments. For example, the Mode data may include information related to the different operating modes such as, but not limited to, the data packet type, the type of battery used, diagnostic routines, single sensor or multiple sensor input, or type of data transmission (RF communication link or other data link such as serial connection). Further, the Glucose 1-slope data may include an 8-bit scaling factor or calibration data for first sensor (scaling factor for sensor **1** data), while Glucose 2-slope data may include an 8-bit scaling factor or calibration data for the second analyte sensor (in the embodiment including more than one analyte sensors).

In addition, the Ref-R data may include 12 bits of on-board reference resistor used to calibrate the temperature measurement in the thermistor circuit (where 8 bits are transmitted in time slot **3**, and the remaining 4 bits are transmitted in time slot **4**), and the 20-bit Hobbs counter data may be separately transmitted in three time slots (for example, in time slot **4**, time slot **5** and time slot **6**) to add up to 20 bits. In one embodiment, the Hobbs counter may be configured to count each occurrence of the data transmission (for example, a packet transmission at approximately 60 second intervals) and may be incremented by a count of one (1).

In one aspect, the Hobbs counter is stored in a nonvolatile memory of the transmitter unit **102** (FIG. **1**) and may be used to ascertain the power supply status information such as, for example, the estimated battery life remaining in the transmitter unit **102**. That is, with each sensor replacement, the Hobbs counter is not reset, but rather, continues the count with each replacement of the sensor **101** to establish contact with the transmitter unit **102** such that, over an extended usage time period of the transmitter unit **102**, it may be possible to determine, based on the Hobbs count information, the amount of consumed battery life in the transmitter unit **102**, and also, an estimated remaining life of the battery in the transmitter unit **102**.

That is, in one embodiment, the 20 bit Hobbs counter is incremented by one each time the transmitter unit **102** transmits a data packet (for example, approximately each 60 seconds), and based on the count information in the Hobbs counter, in one aspect, the battery life of the transmitter unit **102** may be estimated. In this manner, in configurations of the transmitter unit **620** (see FIG. **6**) where the power supply is not a replaceable component but rather, embedded within the housing the transmitter unit **620**, it is possible to estimate the remaining life of the embedded battery within the transmitter unit **620**. Moreover, the Hobbs counter is configured to remain persistent in the memory device of the transmitter unit **620** such that, even when the transmitter unit power is turned off or powered down (for example, during the periodic sensor replacement, RF transmission turned off period and the like), the Hobbs counter information is retained.

Referring to Table 5 above, the transmitted rolling data may also include 8 bits of sensor count information (for example, transmitted in time slot **7**). The 8 bit sensor counter is incremented by one each time a new sensor is connected to the transmitter unit. The ASIC configuration of the transmitter unit (or a microprocessor based transmitter configuration or with discrete components) may be configured to store in a nonvolatile memory unit the sensor count information and transmit it to the primary receiver unit **104** (for example). In turn, the primary receiver unit **104** (and/or the secondary receiver unit **106**) may be configured to determine whether it is receiving data from the transmitter unit that is associated with the same sensor (based on the sensor count information), or from a new or replaced sensor (which will have a sensor count incremented by one from the prior sensor count). In this manner, in one aspect, the receiver unit (primary or secondary) may be configured to prevent reuse of the same sensor by the user based on verifying the sensor count information associated with the data transmission received from the transmitter unit **102**. In addition, in a further aspect, user notification may be associated with one or more of these parameters. Further, the receiver unit (primary or secondary) may be configured to detect when a new sensor has been inserted, and thus prevent erroneous application of one or more calibration parameters determined in conjunction with a prior sensor, that may potentially result in false or inaccurate analyte level determination based on the sensor data.

FIG. **4** is a flowchart illustrating a data packet procedure including rolling data for transmission in accordance with one embodiment of the present invention. Referring to FIG. **4**, in one embodiment, a counter is initialized (for example, to T=0) (**410**). Thereafter the associated rolling data is retrieved from memory device, for example (**420**), and also, the time sensitive or urgent data is retrieved (**430**). In one embodiment, the retrieval of the rolling data (**420**) and the retrieval of the time sensitive data (**430**) may be retrieved at substantially the same time.

Referring back to FIG. **4**, with the rolling data and the time sensitive data, for example, the data packet for transmission is generated (**440**), and upon transmission, the counter is incremented by one (**450**) and the routine returns to retrieval of the rolling data (**420**). In this manner, in one embodiment, the urgent time sensitive data as well as the non-urgent data may be incorporated in the same data packet and transmitted by the transmitter unit **102** (FIG. **1**) to a remote device such as one or more of the receivers **104**, **106**. Furthermore, as discussed above, the rolling data may be updated at a predetermined time interval which is longer than the time interval for each data packet transmission from the transmitter unit **102** (FIG. **1**).

FIG. **5** is a flowchart illustrating data processing of the received data packet including the rolling data in accordance with one embodiment of the present invention. Referring to FIG. **5**, when the data packet is received (**510**) (for example, by one or more of the receivers **104**, **106**, in one embodiment), the received data packet is parsed so that the urgent data may be separated from the not-urgent data (stored in, for example, the rolling data field in the data packet) (**520**). Thereafter the parsed data is suitably stored in an appropriate memory or storage device (**530**).

In the manner described above, in accordance with one embodiment of the present invention, there is provided method and apparatus for separating non-urgent type data (for example, data associated with calibration) from urgent type data (for example, monitored analyte related data) to be transmitted over the communication link to minimize the potential burden or constraint on the available transmission time. More specifically, in one embodiment, non-urgent data may be separated from data that is required by the communication system to be transmitted immediately, and transmitted over the communication link together while maintaining a minimum transmission time window. In one embodiment, the non-urgent data may be parsed or broken up in to a number of data segments, and transmitted over multiple data packets. The time sensitive immediate data (for example, the analyte sensor data, temperature data, etc.), may be transmitted over the communication link substantially in its entirety with each data packet or transmission.

FIG. **6** is a block diagram illustrating the sensor and the transmitter unit of the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention. Referring to FIG. **6**, in one aspect, a transmitter unit **620** is provided in a substantially water tight and sealed housing. The transmitter unit **620** includes respective contacts (WRK, REF, CNTR, and GRD) for respectively establishing electrical contact with one or more of the working electrode, the reference electrode, the counter electrode and the ground terminal (or guard trace) of the sensor **610**. Also shown in FIG. **6** is a conductivity bar/trace **611** provided on the sensor **610**. For example, in one embodiment, the conductivity bar/trace **611** may comprise a carbon trace on a substrate layer of the sensor **610**. In this manner, in one embodiment, when the sensor **610** is coupled to the transmitter unit **620**, electrical contact is established, for example, via the conductivity bar/trace **611** between the contact pads or points of the transmitter unit **620** (for example, at the counter electrode contact (CNTR) and the ground terminal contact (GRD) such that the transmitter unit **620** may be powered for data communication.

That is, during manufacturing of the transmitter unit **620**, in one aspect, the transmitter unit **620** is configured to include a power supply such as battery **621**.

Further, during the initial non-use period (e.g., post manufacturing sleep mode), the transmitter unit **620** is configured such that it is not used and thus drained by the components of the transmitter unit **620**. During the sleep mode, and prior to establishing electrical contact with the sensor **610** via the conductivity bar/trace **611**, the transmitter unit **620** is provided with a low power signal from, for example, a low power voltage comparator **622**, via an electronic switch **623** to maintain the low power state of, for example, the transmitter unit **620** components. Thereafter, upon connection with the sensor **610**, and establishing electrical contact via the conductivity bar/trace **611**, the embedded power supply **621** of the transmitter unit **620** is activated or powered up so that some of all of the components of the transmitter unit **620** are configured to receive the necessary power signals for operations related to, for example, data communication, processing and/or storage.

In one aspect, since the transmitter unit **620** is configured to a sealed housing without a separate replaceable battery compartment, in this manner, the power supply of the battery **621** is preserved during the post manufacturing sleep mode prior to use.

In a further aspect, the transmitter unit **620** may be disposed or positioned on a separate on-body mounting unit that may include, for example, an adhesive layer (on its bottom surface) to firmly retain the mounting unit on the skin of the user, and which is configured to receive or firmly position the transmitter unit **620** on the mounting unit during use. In one aspect, the mounting unit may be configured to at least partially retain the position of the sensor **610** in a transcutaneous manner so that at least a portion of the sensor is in fluid contact with the analyte of the user. Example embodiments of the mounting or base unit and its cooperation or coupling with the transmitter unit are provided, for example, in U.S. Pat. No. 6,175,752, incorporated herein by reference for all purposes.

In such a configuration, the power supply for the transmitter unit **620** may be provided within the housing of the mounting unit such that, the transmitter unit **620** may be configured to be powered on or activated upon placement of the transmitter unit **620** on the mounting unit and in electrical contact with the sensor **610**. For example, the sensor **610** may be provided pre-configured or integrated with the mounting unit and the insertion device such that, the user may position the sensor **610** on the skin layer of the user using the insertion device coupled to the mounting unit. Thereafter, upon transcutaneous positioning of the sensor **610**, the insertion device may be discarded or removed from the mounting unit, leaving behind the transcutaneously positioned sensor **610** and the mounting unit on the skin surface of the user.

Thereafter, when the transmitter unit **620** is positioned on, over or within the mounting unit, the battery or power supply provided within the mounting unit is configured to electrically couple to the transmitter unit **620** and/or the sensor **610**.

Given that the sensor **610** and the mounting unit are provided as replaceable components for replacement every 3, 5, 7 days or other predetermined time periods, the user is conveniently not burdened with verifying the status of the power supply providing power to the transmitter unit **620** during use. That is, with the power supply or battery replaced with each replacement of the sensor **610**, a new power supply or battery will be provided with the new mounting unit for use with the transmitter unit **620**.

Referring to FIG. **6** again, in one aspect, when the sensor **610** is removed from the transmitter unit **620** (or vice versa), the electrical contact is broken and the conductivity bar/trace **611** returns to an open circuit. In this case, the transmitter unit **620** may be configured, to detect such condition and generate a last gasp transmission sent to the primary receiver unit **104** (and/or the secondary receiver unit **106**) indicating that the sensor **610** is disconnected from the transmitter unit **620**, and that the transmitter unit **620** is entering a powered down (or low power off) state. And the transmitter unit **620** is powered down into the sleep mode since the connection to the power supply (that is embedded within the transmitter unit **620** housing) is broken.

In this manner, in one aspect, the processor **624** of the transmitter unit **620** may be configured to generate the appropriate one or more data or signals associated with the detection of sensor **610** disconnection for transmission to the receiver unit **104** (FIG. **1**), and also, to initiate the power down procedure of the transmitter unit **620**. In one aspect, the components of the transmitter unit **620** may be configured to include application specific integrated circuit (ASIC) design with one or more state machines and one or more nonvolatile and/or volatile memory units such as, for example, EEPROMs and the like.

Referring again to FIGS. **1** and **6**, in one embodiment, the communication between the transmitter unit **620** (or **102** of FIG. **1**) and the primary receiver unit **104** (and/or the secondary receiver unit **106**) may be based on close proximity communication where bi-directional (or uni-directional) wireless communication is established when the devices are physically located in close proximity to each other. That is, in one embodiment, the transmitter unit **620** may be configured to receive very short range commands from the primary receiver unit **104** (FIG. **1**) and perform one or more specific operations based on the received commands from the receiver unit **104**.

In one embodiment, to maintain secure communication between the transmitter unit and the data receiver unit, the transmitter unit ASIC may be configured to generate a unique close proximity key at power on or initialization. In one aspect, the 4 or 8 bit key may be generated based on, for example, the transmitter unit identification information, and which may be used to prevent undesirable or unintended communication. In a further aspect, the close proximity key may be generated by the receiver unit based on, for example, the transmitter identification information received by the transmitter unit during the initial synchronization or pairing procedure of the transmitter and the receiver units.

Referring again to FIGS. **1** and **6**, in one embodiment, the transmitter unit ASIC configuration may include a 32 KHz oscillator and a counter which may be configured to drive the state machine in the transmitter unit ASIC. The transmitter ASIC configuration may include a plurality of close proximity communication commands including, for example, new sensor initiation, pairing with the receiver unit, and RF communication control, among others. For example, when a new sensor is positioned and coupled to the transmitter unit so that the transmitter unit is powered on, the transmitter unit is configured to detect or receive a command from the receiver unit positioned in close proximity to the transmitter unit. For example, the receiver unit may be positioned within a couple of inches of the on-body position of the transmitter unit, and when the user activates or initiates a command associated with the new sensor initiation from the receiver unit, the transmitter unit is configured to receive the command from the receiver and, in its response data packet, transmit, among others, its identification information back to the receiver unit.

In one embodiment, the initial sensor initiation command does not require the use of the close proximity key. However, other predefined or preconfigured close-proximity commands may be configured to require the use of the 8 bit key (or a key of a different number of bits). For example, in one embodiment, the receiver unit may be configured to transmit a RF on/off command to turn on/off the RF communication module or unit in the transmitter unit **102**. Such RF on/off command in one embodiment includes the close proximity key as part of the transmitted command for reception by the transmitter unit.

During the period that the RF communication module or unit is turned off based on the received close proximity command, the transmitter unit does not transmit any data, including any glucose related data. In one embodiment, the glucose related data from the sensor which are not transmitted by the transmitter unit during the time period when the RF communication module or unit of the transmitter unit is turned off may be stored in a memory or storage unit of the transmitter unit for subsequent transmission to the receiver unit when the transmitter unit RF communication module or unit is turned back on based on the RF-on command from the receiver unit. In this manner, in one embodiment, the transmitter unit may be powered down (temporarily, for example, during air travel) without removing the transmitter unit from the on-body position.

FIG. **7** is a flowchart illustrating data communication using close proximity commands in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention. Referring to FIG. **7**, the primary receiver unit **104** (FIG. **1**) in one aspect may be configured to retrieve or generate a close proximity command (**710**) for transmission to the transmitter unit **102**. To establish the transmission range (**720**), the primary receiver unit **104** may be positioned physically close to (that is, within a predetermined distance from) the transmitter unit **102**. For example, the transmission range for the close proximity communication may be established at approximately one foot distance or less between the transmitter unit **102** and the primary receiver unit **104**. When the transmitter unit **102** and the primary receiver unit **104** are within the transmission range, the close proximity command, upon initiation from the receiver unit **104** may be transmitted to the transmitter unit **102** (**730**).

Referring back to FIG. **7**, in response to the transmitted close proximity command, a response data packet or other responsive communication may be received (**740**). In one aspect, the response data packet or other responsive communication may include identification information of the transmitter unit **102** transmitting the response data packer or other response communication to the receiver unit **104**. In one aspect, the receiver unit **104** may be configured to generate a key (for example, an 8 bit key or a key of a predetermined length) based on the transmitter identification information (**750**), and which may be used in subsequent close proximity communication between the transmitter unit **102** and the receiver unit **104**.

In one aspect, the data communication including the generated key may allow the recipient of the data communication to recognize the sender of the data communication and confirm that the sender of the data communication is the intended data sending device, and thus, including data which is desired or anticipated by the recipient of the data communication. In this manner, in one embodiment, one or more close proximity commands may be configured to include the generated key as part of the transmitted data packet. Moreover, the generated key may be based on the transmitter ID or other suitable unique information so that the receiver unit **104** may use such information for purposes of generating the unique key for the bidirectional communication between the devices.

While the description above includes generating the key based on the transmitter unit **102** identification information, within the scope of the present disclosure, the key may be generated based on one or more other information associated with the transmitter unit **102**, and/or the receiver unit combination. In a further embodiment, the key may be encrypted and stored in a memory unit or storage device in the transmitter unit **102** for transmission to the receiver unit **104**.

FIG. **8** is a flowchart illustrating sensor insertion detection routine in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention. Referring to FIG. **8**, connection to an analyte sensor is detected (**810**) based on, for example, a power up procedure where the sensor conduction trace **611** (FIG. **6**) is configured to establish electrical contact with a predetermined one or more contact points on the transmitter unit **102**. That is, when the sensor **101** (for example, the electrodes of the sensor) is correspondingly connected to the contact points on the transmitter unit **102**, the transmitter unit **102** is configured to close the circuit connecting its power supply (for example, the battery **621** (FIG. **6**)) to the components of the transmitter unit **102** and thereby exiting the power down or low power state into active or power up state.

In this manner, as discussed above, in one aspect, the transmitter unit **102** may be configured to include a power supply such as a battery **621** integrally provided within the sealed housing of the transmitter unit **102**. When the transmitter unit **102** is connected or coupled to the respective electrodes of the analyte sensor that is positioned in a transcutaneous manner under the skin layer of the patient, the transmitter unit **102** is configured to wake up from its low power or sleep state (**820**), and power up the various components of the transmitter unit **102**. In the active state, the transmitter unit **102** may be further configured to receive and process sensor signals received from the analyte sensor **101** (FIG. **1**) (**830**), and thereafter, transmit the processed sensor signals (**840**) to, for example, the receiver unit **104** (FIG. **1**).

Accordingly, in one aspect, the sensor **610** (FIG. **6**) may be provided with a conduction trace **611** which may be used to wake up or exit the transmitter unit from its post manufacturing sleep mode into an active state, by for example, establishing a closed circuit with the power supply provided within the transmitter unit **102**.

FIG. **9** is a flowchart illustrating sensor removal detection routine in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention. Referring to FIG. **9**, when the sensor removal is detected (**910**) for example, based on detaching or removing the transmitter unit **102** that was in contact with the sensor **101**, one or more status signal is generated (**920**), that includes, for example, an indication that the sensor removal state has been detected, and/or an indication that the transmitter unit **102** will enter a sleep mode or a powered down status. Thereafter, the generated status signal in one aspect is transmitted, for example, to the receiver unit **104** (**930**), and the transmitter unit **102** is configured to enter the power down mode or low power sleep mode (**940**).

In this manner, in one aspect, when the transmitter unit **102** is disconnected from an active sensor **101**, the transmitter unit **102** is configured to notify the receiver unit **104** that the sensor **101** has been disconnected or otherwise, signals from the sensor **101** are no longer received by the transmitter unit **102**. After transmitting the one or more signals to notify the receiver unit **104**, the transmitter unit **102** in one embodiment is configured to enter sleep mode or low power state during which no data related to the monitored analyte level is transmitted to the receiver unit **104**.

FIG. **10** is a flowchart illustrating the pairing or synchronization routine in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention. Referring to FIG. **10**, in one embodiment, the transmitter unit **102** may be configured to receive a sensor initiate close proximity command (**1010**) from the receiver unit **104** positioned within the close transmission range. Based on the received sensor initiate command, the transmitter unit identification information may be retrieved (for example, from a nonvolatile memory) and transmitted (**1020**) to the receiver unit **104** or the sender of the sensor initiate command.

Referring back to FIG. **10**, a communication key optionally encrypted is received in one embodiment (**1030**), and thereafter, sensor related data is transmitted with the communication key on a periodic basis such as, every 60 seconds, five minutes, or any suitable predetermined time intervals (**1040**).

Referring now to FIG. **11**, a flowchart illustrating the pairing or synchronization routine in the data monitoring and management system of FIG. **1** in accordance with another embodiment of the present invention is shown. That is, in one aspect, FIG. **11** illustrates the pairing or synchronization routine from the receiver unit **104**. Referring back to FIG. **11**, the sensor initiate command is transmitted to the transmitter unit **102** (**1110**) when the receiver unit **104** is positioned within a close transmission range. Thereafter, in one aspect, the transmitter identification information is received (**1120**) for example, from the transmitter unit that received the sensor initiate command. Thereafter, a communication key (optionally encrypted) may be generated and transmitted (**1130**) to the transmitter unit.

In the manner described above, in one embodiment, a simplified pairing or synchronization between the transmitter unit **102** and the receiver unit **104** may be established using, for example, close proximity commands between the devices. As described above, in one aspect, upon pairing or synchronization, the transmitter unit **102** may be configured to periodically transmit analyte level information to the receiver unit **104** for further processing.

FIG. **12** is a flowchart illustrating the power supply determination in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention. That is, in one embodiment, using a counter, the receiver unit **104** may be configured to determine the power supply level of the transmitter unit **102** battery so as to determine a suitable time for replacement of the power supply or the transmitter unit **102** itself. Referring to FIG. **12**, periodic data transmission is detected (**1210**), and a corresponding count in the counter is incremented for example, by one with each detected data transmission (**1220**). In particular, a Hobbs counter may be used in the rolling data configuration described above to provide a count that is associated with the transmitter unit data transmission occurrence.

Referring to FIG. **12**, the updated or incremented count stored in the Hobbs counter is periodically transmitted in the data packet (**1230**) from the transmitter unit **102** to the receiver unit **104**. Moreover, the incremented or updated count may be stored (**1240**) in a persistent nonvolatile memory unit of the transmitter unit **102**. Accordingly, based on the number of data transmission occurrences, the battery power supply level may be estimated, and in turn, which may provide an indication as to when the battery (and thus the transmitter unit in the embodiment where the power supply is manufactured to be embedded within the transmitter unit housing) needs to be replaced.

Moreover, in one aspect, the incremented count in the Hobbs counter is stored in a persistent nonvolatile memory such that, the counter is not reset or otherwise restarted with each sensor replacement.

FIG. **13** is a flowchart illustrating close proximity command for RF communication control in the data monitoring and management system of FIG. **1** in accordance with one embodiment of the present invention. Referring to FIG. **13**, a close proximity command associated with communication status, for example is received (**1310**). In one aspect, the command associated with the communication status may include, for example, a communication module turn on or turn off command for, for example, turning on or turning off the associated RF communication device of the transmitter unit **102**. Referring to FIG. **13**, the communication status is determined (**1320**), and thereafter, modified based on the received command (**1330**).

That is, in one aspect, using one or more close proximity commands, the receiver unit **104** may be configured to control the RF communication of the transmitter unit **102** to, for example, disable or turn off the RF communication functionality for a predetermined time period. This may be particularly useful when used in air travel or other locations such as hospital settings, where RF communication devices need to be disabled. In one aspect, the close proximity command may be used to either turn on or turn off the RF communication module of the transmitter unit **102**, such that, when the receiver unit **104** is positioned in close proximity to the transmitter unit **102**, and the RF command is transmitted, the transmitter unit **102** is configured, in one embodiment, to either turn off or turn on the RF communication capability of the transmitter unit **102**.

FIG. **14** is a flowchart illustrating analyte sensor identification routine in accordance with one embodiment of the present invention. Referring to FIG. **14**, periodically, sensor counter information is received (**1410**), for example included as rolling data discussed above. The received sensor counter information may be stored in one or more storage units such as a memory unit. When the sensor counter information is received, a stored sensor counter information is retrieved (**1420**), and the retrieved sensor counter information is compared with the received sensor counter information (**1430**). Based on the comparison between the retrieved sensor counter information and the received sensor counter information, one or more signal is generated and output (**1440**). That is, in one aspect, the sensor counter in the transmitter unit **102** may be configured to increment by one with each new sensor replacement. Thus, in one aspect, the sensor counter information may be associated with a particular sensor from which monitored analyte level information is generated and transmitted to the receiver unit **104**. Accordingly, in one embodiment, based on the sensor counter information, the receiver unit **104** may be configured to ensure that the analyte related data is generated and received from the correct analyte sensor transmitted from the transmitter unit **102**. A method in one embodiment includes detecting a data transmission, incrementing a count associated with the detected data transmission, and storing the count. The count may be incremented by one. In a further aspect, the method may include associating a power supply level information with the stored count.

Moreover, the method may also include generating a signal associated with the stored count, and/or include outputting the generated signal, where outputting the generated signal may include one or more of visually displaying the generated signal, audibly outputting the generated signal, or vibratory outputting the generated signal.

In yet another aspect, the method may include transmitting the count with the data transmission, where the count may be transmitted periodically with the data transmission.

In still another aspect, the method may include associating a power supply status with the count.

A data processing device in another embodiment may include a counter, a data communication unit, and a data processing section coupled to the data communication unit and the counter, the data processing section configured to increment a count stored in the counter based on data transmission by the data communication unit.

In one aspect, the counter may include a nonvolatile memory unit. The counter may include an EEPROM. The data communication unit may include an RF transceiver. The count stored in the counter may be incremented by one with each data transmission by the data communication unit.

The device may include a power supply coupled to the data processing unit, the data communication unit and the counter, where the count stored in the counter is not erased when the power supply is disabled or in low power state.

The data processing unit may be configured to estimate the power supply life based on the stored count in the counter. The device in a further aspect may include an output section for outputting one or more signals associated with the count information, where the output section may include one or more of a display unit, an audible output section, or a vibratory output section.

In accordance with another aspect of the invention, elapsed sensor life and/or remaining sensor life is determinable. In this regard the sensor life is tracked by a counter. Advantageously, after a system failure such as power shutdown, power loss, reset (e.g., Watchdog reset), battery drain, battery failure, the user of the data monitoring and management system of FIG. **1** no longer needs to replace the sensor. Instead, the methods and system of the invention provide sensor life information to the user to enable the user to restart the analyte monitoring system using the same sensor, provided suitable remaining sensor life.

In one embodiment of the invention, as shown in FIG. **1**, an analyte monitoring and management system includes an analyte sensor **101**, a transmitter unit **102**, a first counter (not shown), such as a Hobbs counter, and a receiver unit **104**. The system can be configured to determine the elapsed life (or remaining life) of an employed analyte sensor **101**. Advantageously, a user of the analyte monitoring system is now able to determine a suitable time for replacement of the analyte sensor, for example, in the event of a system failure during which the receiver loses data information about calibration schedule and/or sensor expiration schedule. Prior systems typically require the user to discard the analyte sensor (regardless of remaining life available on the sensor) after the occurrence of a system failure due to the data loss of time and day and calibration.

In accordance with one embodiment of the method, a signal associated with initiation of an analyte sensor is provided. For example, but not limitation, upon initiation of the sensor **101** a signal is generated which contains analyte measurement information. The signal can be at least part of the data which forms a data packet that is encoded by the transmitter unit **102** and/or transmitted via a communication link to a receiver unit **104**. The receiver unit **104** can be configured to expect receipt of a data packet at predetermined time intervals and/or at periodic calculations of analyte. In one embodiment, the data packets are transmitted by a transmitter unit **102** to receiver unit **104** every minute. After the count temporally associated with initiation of the sensor is stored, the counter is configured to continually count by increments. The increments can be for example, based on a periodic cycle, such as a measurement cycle. Alternatively, the increment can be based on other factors, such as scheduled time interval. Additionally, the incremental count can be commensurate with the transmission of each (or a predetermined limited number) data packets and/or measurement cycles. Thus, for example, the measurement cycle can be a periodic calculation of measured analyte (regardless of whether it is transmitted), or it can be based on a selected time interval, such as for example 30 or 60 seconds, if desired. In some embodiments, the count information incrementally counted by the counter is transmitted to the receiver unit **104** as part of the data packet. Further, the receiver is configured to extract the count from the data packet.

In one embodiment, the count information transmitted in the data packet upon sensor initiation is transmitted to receiver unit **104** where it is stored. Preferably, the count information is stored in nonvolatile memory such that it is not lost during a system failure. Preferably, the nonvolatile memory device is disposed in the receiver unit **104**. However, transmitter unit **102** can be configured to store the count. The counter which can be part of the transmitter device **102**, for example, is a Hobbs counter.

In accordance with one embodiment of the invention, elapsed life of an analyte sensor (or remaining life expectancy of a sensor) can be determined by comparing the stored count which is based on sensor initiation with an incremented count. As described above, the incremental count is based on a known measurement cycle, and/or time interval. Thus, the comparison of the count information can be used to calculate the duration or elapsed time of the sensor use.

Further, the determined elapsed time can be used to restart operating system timers, such as a sensor life timer and/or calibration timer.

FIG. **15** is a flowchart illustrating a method for determining elapsed life of an analyte sensor employed in the analyte monitoring and management system of FIG. **1**. As depicted and embodied herein, an analyte sensor is initiated (**1510**) to detect and/or measure the presence of an analyte in a bodily fluid. For the purpose of illustration, but not limitation, the analyte can be glucose and the bodily fluid can be blood, plasma or interstitial fluid. However, other analytes can be monitored, such as but not limited to lactate. A counter, such as for example a Hobbs counter described above, is configured to incrementally count. The Hobbs counter may be disposed for example in the transmitter of the analyte monitoring system. The count or value that is temporally associated with the initiation of the sensor (**1520**) (or a signal generated by the sensor during initiation) is stored in a memory unit (count 1) (**1530**). In addition to the storage of the first count, the counter continues to incrementally count. As described, the incremental count can be based on a known measurement cycle, such as that of the analyte sensor detecting levels of an analyte in the bodily fluid. Alternatively, the incremental count can be based on a time interval. In the event that a system failure occurs, the counter is configured to store a second count temporally associated with re-initiation of the analyte sensor (count 2) (**1540**). In this regard, the elapsed time or duration of use of the analyte sensor prior to the fault condition can be determined by comparing count 2 and count 1 (**1550**). Thus, provided that at least some life expectancy of the analyte sensor remains, the user may continue to use the analyte sensor, rather than being required to change the sensor with a replacement sensor because all data was lost. In the event that no or less than a predetermined amount of life remains on the analyte sensor, the monitoring system can be configured to display a message or alarm that the sensor expired or is soon to expire (**1560**). In a further embodiment, the determined elapsed time can be used to restart a sensor life timer and/or calibration timer (**1570**).

The term system failure as used herein means a fault condition such as any condition by which the analyte monitoring system loses power. Some non-limiting examples of fault conditions include a reset (e.g., receiver reset), battery drain, battery replacement, power loss, power shut-down, or a fatal error. Typically, after such fault conditions, analyte monitoring systems prompt the user to replace the sensor because information about the life of the sensor was lost at the time of the fault condition. This aspect of the invention, allows the use of the same sensor after a fault condition occurs (provided that the sensor life has not expired), thereby saving the user costs associated with using a new sensor and the hardship of undergoing another calibration schedule.

In another embodiment of the invention, the analyte monitoring and management system includes a first counter to incrementally count based on a time interval, or calculation of an analyte, and a second counter to incrementally count by one only if a new sensor is initiated. In this regard, the incremental count of the second sensor can indicate how many or which sensor is being employed. For example, if the second counter has an incremental count of one, then the first sensor is being employed, if the second counter has an incremental count of 2, then the second sensor is being employed. Thus, the second counter can track how many sensors have been employed. In a further aspect of the invention, if the receiver connects to the transmitter and in response the receiver receives a count change compared to the sensor count before the system failure, the receiver acknowledges that a different sensor was implanted or otherwise employed during the receiver shut down. In this regard, the previous sensor life time is terminated, and a new count begins for the new sensor. Additionally, when the second counter increments by one because a new sensor is used then the count of the first counter is stored.

Referring to another embodiment of the invention, as described in FIG. **16**, the first counter can be a Hobbs counter which is initiated (for example, to T=0) (**1610**). Thereafter the Hobbs counter incrementally counts (for example, to T=T+1) (**1620**). The second counter can be for example a sensor counter that is configured to count incrementally with the initiation of each new analyte sensor (for example, S=S+1) (**1640**). Thus, if there is no new sensor employed, the count of the second counter does not increment (**1630**). Further, a count of the Hobbs counter (**1650**) (which is commensurate with an incremental count of the sensor counter) is stored (**1660**). Thus, the system contains stored data regarding the data and time of each new sensor initiation. Accordingly, the first and second counters in conjunction can be used to determine elapsed life of the analyte sensor. As shown in FIG. **16**, if the sensor life is less than the sensor life expectancy (**1670**), then the cycle is repeated. If the sensor life is expired or close to its expiration, then an alarm or message can be output (**1680**).

In one embodiment, the first counter is a 20-bit counter, and the second counter is an 8-bit counter. However, other types of counters can be utilized.

In another aspect of the invention, an output unit is provided. The output unit can be configured to display a value derived from the count information. In this regard, the output unit can be a display device. The display device can be an Organic Light Emitting Diode (OLED) display device, for example, a small molecule or polymer OLED. The OLED display device can provide wide viewing angles, high brightness, colors, and contrast levels.

It will be apparent to those skilled in the art that various modifications and alterations in the methods and systems of this invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. It is intended that the following claims define the scope of the present invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

**1**. A method, comprising:

providing a signal associated with initiation of an analyte sensor, the analyte sensor for monitoring analyte level;

providing a count, wherein the count is temporally associated with the signal associated with the initiation of the analyte sensor;

periodically incrementing the count;

storing the count temporally associated with the signal associated with the initiation of the analyte sensor, wherein when sensor life of the initiated analyte sensor has not expired and a system failure is detected, continuing use of the initiated analyte sensor based at least in part on the stored count;

providing a new sensor count; and

incrementing the new sensor count only when a new sensor is first initiated.

**2**. The method of claim **1**, wherein incrementing the count is associated with a measurement cycle.

**3**. The method of claim **2**, wherein the measurement cycle comprises a periodic determination of the monitored analyte level.

**4**. The method of claim **1**, including storing the count temporally associated with the initiation of the analyte sensor in a memory device.

**5**. The method of claim **4**, wherein the memory device is a nonvolatile memory device, such that count information stored in the memory is not lost during the system failure.

**6**. The method of claim **1**, wherein the system failure is a component failure.

**7**. The method of claim **1**, wherein the system failure includes a battery drain, power shut-down, or reset.

**8**. The method of claim **1**, including outputting a message or alarm when the system failure occurs.

**9**. The method of claim **1**, wherein incrementing the count is associated with communication of data packets.

**10**. The method of claim **1**, wherein the analyte sensor comprises a working electrode that includes an analyte responsive enzyme and a mediator, wherein at least one of the analyte responsive enzyme and the mediator is chemically bonded to a polymer disposed on the working electrode, and wherein at least one of the analyte responsive enzyme and the mediator is crosslinked with the polymer.

**11**. A data processing device, comprising:

a first counter configured to incrementally count;

a data communication unit;

a data processing section coupled to the data communication unit and the first counter, the data processing section configured to determine an elapsed life of an analyte sensor;

wherein when a device failure is detected and the determined elapsed life indicates that analyte sensor life has not expired, continuing use of the analyte sensor based at least in part on the first counter configured to incrementally count; and

a new sensor counter coupled to the data processing section and configured to increment a new sensor count only when a new sensor is first initiated.

**12**. The data processing device of claim **11**, wherein the analyte sensor is configured to generate a signal associated with a level of monitored analyte.

**13**. The data processing device of claim **11**, further including a storage unit configured to store a count temporally associated with initiation of the analyte sensor.

**14**. The data processing device of claim **11**, wherein the analyte sensor includes a glucose sensor.

**15**. The data processing device of claim **13**, wherein the data processing section is configured to compare the stored count with an incremented count associated with the first counter to determine the elapsed life of the analyte sensor.

**16**. The data processing device of claim **15**, wherein the data processing section is configured to estimate the remaining sensor life based on the stored count and the incremented count.

**17**. The data processing device of claim **13**, further including an output unit configured to output one or more signals associated with the count.

**18**. The data processing device of claim **13**, wherein the analyte sensor comprises a working electrode that includes an analyte responsive enzyme and a mediator, wherein at least one of the analyte responsive enzyme and the mediator is chemically bonded to a polymer disposed on the working electrode, and wherein at least one of the analyte responsive enzyme and the mediator is crosslinked with the polymer.

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